UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CYTYC CORPORATION, Plaintiff,	)	
v.	)	CIVIL ACTION NO. 03-11142-DPW [Lead case]
TRIPATH IMAGING, INC., Defendant.	)	

TRIPATH IMAGING, INC., Plaintiff,	)	
v.	)	CIVIL ACTION NO. 03-12630-DPW
CYTYC CORPORATION, Defendant.	)	

MEMORANDUM AND ORDER
August 22, 2007

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In these consolidated actions, Cytyc Corporation ("Cytyc") seeks declaratory judgment that its ThinPrep Imaging System ("TIS") does not infringe four patents owned by TriPath Imaging, Inc. ("TriPath") regarding the semi-automated screening of biological samples for cancerous cells: United States Patent Nos. 6,327,377 ("'377 patent"), 5,257,182 ("'182 patent"), 5,715,327 ("'327 patent"), and 5,793,969 ("'969 patent"). Cytyc also requests a declaration that the patents are invalid. TriPath, in turn, claims that Cytyc's TIS infringes TriPath's patents.

Both parties have moved for summary judgment as to certain claims. Cytyc moves for a judgment of noninfringement and invalidity with respect to the '377, '183, and '327 patents and noninfringement with respect to the '969 patent. Tripath moves for a judgment of nonanticipation for each patent and literal infringement with respect to the '327 patent. For the reasons stated below, I grant in part and deny in part the motions for summary judgment of both parties.

I. BACKGROUND

The technology in this case centers around the process of screening biological material for the presence of abnormal or cancerous cells.

A. Cytyc's Technology

Cervical cancer is screened by examining cervical tissue most often taken in the form of a Papancolaou ("Pap") smear. The screening of slides of thousands of cells can be tedious and time consuming. Cytyc's TIS is an automated microscope that aids physicians in identifying whether a slide contains cancerous cells. It uses computer imaging technology to search for the presence of atypical cells, cervical neoplasia, carcinoma, and other cytologic criteria. The TIS reduces time spent screening slides by presenting the cytologist with the portions of the slide most likely to contain abnormal cells, eliminating the need for the cytologist to review the entire slide.

The TIS consists of two components: the Image Processor Subsystem and the Review Scope. The Image Processor Subsystem is a computer-controlled microscopic imaging device that determines the cells of greatest abnormality and stores their locations in a database for future access. The Subsystem consists of a monitor, keyboard, and mouse, an Image Processor, and an Image Processor Controller, all of which take and process images of slides of biological material measures the nucleus-like blobs or clusters in each image, and using those measurements, weeds out distracting objects such as debris, blood, and mucus to identify normal or abnormal cells. Then, using the size and darkness of the cells, it ranks them in order of likelihood of abnormality

and presents them to a cytotechnologist.[1] The cytotechnologist is responsible for evaluating the entire field using the Review Scope to assess the abnormality of the cells and specimen.

B. TriPath's Patents

I describe the technology of the several TriPath patents generally at this point and then address the cross-motions for summary judgment relating to each patent in turn in following sections.

1. '377 Patent (Rutenberg)

The '377 Patent (Rutenberg), issued December 4, 2001, claims a "semi-automated" method for screening and classifying cytological specimens.[2] In the preferred embodiment, the Rutenberg device includes an automated microscope, a camera, and a computer. '377 patent at col. 4, ll. 44-47. Rutenberg describes the process of classification of a slide as comprising at least three steps of screening. The first screening (or "primary classifier") of the cells consists of a low resolution scan in which the image processor screens out objects that are too small, too dark, or too light to be malignant. *Id.* at col. 11, ll. 13-15. The secondary screening ("secondary classifier") is a higher resolution scan performed by a computer that identifies suspicious looking cells within the slide. *Id.* at

[1] The measurement of the size and darkness of an object of interest is called the "Integrated Optical Density ("IOD").

[2] The formal title of the patent is "Automated Cytological Specimen Classification System and Method."

col. 11, ll. 24-25. The computer assigns the suspicious looking cells a number from 0.1, for likely benign cells, to 0.9, for likely malignant cells. *Id.* at col. 16, ll. 57 - col. 17, l. 2. The computer then presents the 64 most suspect cells to a cytotechnologist for final classification of the slide. *Id.* at col. 17, ll. 14-15.

2. '182 Patent (Luck)

The '182 patent claims a method of classifying cells based on their morphology, designed to improve the original approach set forth in the '377 patent by providing a better image for the cytotechnician to evaluate. In its preferred embodiment, the device performs three scans of the specimen slides. First, the camera automatically focuses and captures an image of the slide at low magnification. '182 patent, col. 7, ll. 10-13. The image processor then digitizes the image. *Id.* at col. 3, 11. 55-57. In this first scan, the image processor identifies the portions of the slide that contain biological material. *Id.* at col. 7, ll. 14-21. For the second scan, the camera captures at high resolution a second image of the cells identified in the first scan. *Id.* at col. 4, ll. 6-26. The image processor locates the centers of those cells that might be malignant, and a computer assigns the cells a value indicating the likelihood of malignancy. *Id.* Finally, in a high resolution rescan, the camera obtains high resolution images of the sixty-four cells identified in the second scan as the most suspect. *Id.* at col.

4, ll. 27-39. A summary screen displays these images for review by a cytotechnologist. *Id.* at col. 4, ll. 40-43.

3. '327 Patent (Wilhelm)

The '327 patent describes a method and apparatus for determining whether a slide is suitable for processing. '327 patent at col. 2, ll. 3-5. Specifically, the invention determines whether there were errors in specimen collection, slide preparation, slide handling, or machine processing that might lead to an inaccurate diagnosis. *Id.* at col. 2, ll. 8-15. The central computer controls the microscope, camera, and image processor in order to acquire a digital image of the slide. *Id.* at col. 4, ll. 23-26. Then it conducts thirteen suitability tests and computes a score that indicates whether a slide has passed. *Id.* at col. 4, ll. 37-40. In order to produce reliable results, a slide must pass each of the tests. *Id.*

4. '969 Patent (Kamentsky)

The '969 patent describes a network system for review and analysis of computer encoded microscope slides and specimens. '969 patent at col. 5, ll. 10-14. During the initial examination of a slide, a microscope equipped with an encoder device encodes information, such as parts of the slide that have been viewed, events of interest for diagnosis, and, for quality control purposes, the manner in which the initial slide examination was conducted. *Id.* at col. 5, ll. 10-19. This information is stored on a networked file server. *Id.* at col. 5, ll. 14-17.

Users can access this information at a series of microscope

stations linked by a modem or local access network ("LAN"). *Id.* at col. 5, ll. 19-22. In addition, the invention allows users to access images from an online library and patient information while simultaneously viewing a slide, either directly through a microscope or as a stored digital image. *Id.* at col. 5, ll. 19-34.

C. Procedural posture

Plaintiff Cytyc Corporation filed its declaratory judgment action against Defendant TriPath Imaging in this court in June 2003, seeking a finding of invalidity and non-infringement with respect to six TriPath patents.[3] That action, No. 03-11142, which has been designated the lead case, was later consolidated with an infringement action TriPath initially filed against Cytyc in North Carolina and which was transferred to this court as No. 03-12630.

Following a three-day *Markman* hearing, I issued a Memorandum and Order construing disputed claim terms in all four patents-in-suit. Memorandum and Order, November 28, 2005 ("*Markman* Order").

II. LEGAL FRAMEWORK

A. Standard of Review

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no

[3] Cytyc subsequently dropped its claims relating to two of the six patents initially challenged.

genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A judgment as a matter of law is as appropriate in a patent case as it is in any other matter; it is appropriate when no reasonable jury could reach a verdict for the nonmoving party. *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984).

B. Basic Legal Principles

The parties have filed cross motions for summary judgment on issues of patent infringement and patent validity.

An infringement analysis entails two steps: (1) determining the meaning and scope of the patent claims asserted to be infringed and, (2) comparing the properly construed claims to the device accused of infringing. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd,* 512 U.S. 370 (1996). Because I have already construed the meaning and scope of claims in the disputed patents in the *Markman* Order of November 28, 2005, the bulk of the remaining infringement analysis involves the second step.[4]

In order to prove infringement, a patent owner must show that an accused device "incorporates every limitation of a claim, either literally or under the doctrine of equivalents."

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[4] I have as necessary for the resolution of the summary judgment motions made certain revised and additional claim constructions. As in the original *Markman* Order of November 28, 2005 at 66-72, a summary is provided in this memorandum as an Appendix.

Microstrategy, Inc. v. Business Objects, S.A., 429 F.3d 1344, 1352 (Fed. Cir. 2005). To find literal infringement, each claim limitation must be present in the accused device; any deviation precludes such a finding. *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1330 (Fed. Cir. 2001). With respect to methods, "infringement arises when all of the steps of a claimed method are performed, whether or not the infringer also performs additional steps." *Smith & Nephew, Inc. v. Ethicon, Inc.*, 276 F.3d 1304, 1311 (Fed. Cir. 2001). In the absence of literal infringement, the doctrine of equivalents allows patentees "to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 711, 733 (2002).

An accused technology cannot infringe a patent that is invalid. Patents, however, are presumed to be valid. 35 U.S.C. § 282. In order to overcome this presumption, the opposing party must come forward with clear and convincing evidence of invalidity in order to prevail. *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005).

With respect to patent validity, the arguments raised in summary judgment discuss only whether TriPath's four patents were anticipated by prior art. Patent law invalidates claims that have been anticipated by prior art, as defined in 35 U.S.C. § 102. A claim is anticipated "if each and every limitation is found either expressly or inherently in a single prior art

reference." *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1381 (Fed. Cir. 2005). The touchstone of anticipation analysis is "whether one skilled in the art would reasonably understand or infer from the prior art reference's teaching that every claim [limitation] was disclosed in that single reference." *Id.*

With these principles as reference, I address the parties' respective claims after disposition of certain preliminary questions regarding the theories and evidence properly raised in this case.

III. BELATEDLY-DEVELOPED THEORIES

A. Theory of Infringement under the Doctrine of Equivalents

Late in the discovery of this litigation and in contravention of the operative scheduling order, TriPath attempted to introduce the theory of infringement under the doctrine of equivalents for all seventeen asserted claims of the patents-in-suit, including the '182 Luck patent. TriPath first raised the contention explicitly in a "response" expert report on May 2, 2005, two and a half weeks after rebuttal expert reports were due. By Memorandum and Order dated June 21, 2005, I granted Cytyc's motion to strike that portion of the response reports that related to a doctrine of equivalents theory because it was too fundamental a theory not to have been advanced in the initial expert reports. *See* Docket No. 107.

My construction of the word "image" in the November 28, 2005 *Markman* Order appears to have undercut TriPath's claim of literal

infringement on the '182 patent. As a result, TriPath filed a motion to reconsider my July 21, 2005 order (Docket No. 239), arguing (1) that TriPath introduced the doctrine of equivalents theory earlier in litigation than my order states (*i.e.*, that Cytyc had adequate notice), (2) that it would be unduly harsh, prejudicial, and "draconian" for me to prohibit TriPath from proceeding on the equivalents theory of infringement,[5] (3) that any prejudice to Cytyc can be cured by allowing Cytyc to engage in extra discovery, and (4) that as a result TriPath should be able to produce non-expert evidence supporting the doctrine of equivalents.

I will deny TriPath's motion for reconsideration. First, Cytyc did not have adequate notice that TriPath would be advancing a theory of infringement based upon the doctrine of equivalents. I recognize (and noted in 2005) that Cytyc did not ask TriPath in its interrogatories whether it would be pursuing a doctrine of equivalents theory.[6] Thus I believe that the interrogatories and their respective responses are not relevant

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[5] TriPath appears to be alluding to my use of the word "draconian" when denying TriPath's earlier request to strike Cytyc's introduction of the CDS-1000 as prior art. *See* June 21, 2005 Order at 10. I do not consider it draconian to remedy a discovery abuse by excluding the newly introduced discovery that undergirds the abuse. If the remedy seems draconian in hindsight, it is only because TriPath has not been successful on its claim of literal infringement.

[6] The interrogatory that related to the '182 patent did not request TriPath to explain a legal theory of infringement one way or the other. *See* TriPath's Motion to Reconsider, Exhibit B at Interrogatory 3.

to whether Cytyc had or should have had notice. TriPath, however, had the entire length of expert discovery to develop a theory under the doctrine of equivalents. TriPath did make limited reference to the doctrine of equivalents in its initial expert report, by way of legal boilerplate and a few stray references to whether two things were "equivalent" for the purpose of claim construction. *See* TriPath's Motion to Reconsider at 5 (Argument); TriPath's Post-Hearing Supplemental Brief, Exhibit 4 (Initial Expert Report). TriPath claims that raising the theory in this oblique manner constitutes notice. But, as I stated in the July 21, 2005 order, TriPath needed to develop the theory explicitly to place it at issue in the case.

Furthermore, even if my July 21, 2005 order was in some fashion severe, Cytyc has relied upon that judgment through the remaining discovery period. TriPath failed to file a motion to reconsider even after my *Markman* Order entered November 21, 2005. I decline to authorize the parties to engage in additional discovery at this point in the litigation, with trial on the horizon. TriPath claims that any additional discovery Cytyc needs to perform could be completed and briefed without affecting the trial date but I am not persuaded by this bare assertion. Substantial additional discovery will be necessary. Cytyc would have to be allowed to obtain fact discovery on the equivalence of digital and non-digital images, depose TriPath's experts, and serve rebuttal expert reports. Perhaps more importantly, it

would ennervate the integrity of case management deadlines to indulge TriPath's argument that the parties might be able to work harder to remedy the default now that the deadline has passed.

TriPath argues that it should at least be able to present non-expert testimony supporting the doctrine of equivalents. My July 21, 2005 order precluded TriPath from using any evidence at all, not just expert evidence, to advance a theory of doctrine of equivalents. I decline to accept TriPath's suggestion that it can proceed on the equivalents theory using lay testimony. The evidence TriPath wishes to submit is offered to prove whether looking through a microscope is equivalent to looking at a digital image for purposes of the '182 patent. TriPath tenders its experts to testify as "lay witnesses" to this equivalence. Although it is arguable that TriPath does not need expert testimony to prove its claim,[7] I will not allow TriPath to circumvent my June 21, 2005 order by calling an expert to testify under the guise of fact witness testimony.

I realize that the doctrine of equivalents has apparently emerged as TriPath's best argument for infringement of the '182 patent. That development, however, was always a possibility. TriPath did not promptly file a motion to reconsider, not even

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[7] In this connection, TriPath relies on a Report and Recommendation by Magistrate Judge Peck in *Revlon Consumer Products Corp. v. The Estee Lauder Companies, Inc.*, 2003 WL 21751833, *32-33, *39 (S.D.N.Y. July 30, 2003), for the proposition that the nature of the infringement theory -- literal or DOE -- need not be pleaded, and that a DOE theory may be proved without expert reports.

after it had notice that the *Markman* construction excluded a claim for literal infringement. Instead, TriPath waited until filing for summary judgment to raise the doctrine of equivalents theory anew. Meanwhile, in the months after I issued an order striking the theory, Cytyc has relied upon that order and has had no reason to pursue or request additional factual or expert discovery regarding the theory.[8] In order to prevent any possible prejudice Cytyc would suffer by having to respond to a foundational theory of infringement at this late stage of litigation and to maintain the integrity of case management orders and the deadlines they import, I decline to alter my July 21, 2005 order and will deny the motion to reconsider. (Docket No. 239).

Accordingly, Cytyc's corollary motion (Docket No. 214) to strike ¶¶ 3-4 and 19-21 of the Reynolds Declaration (Docket No. 201) and ¶¶ 5-9 of the Gahm Declaration (Docket No. 188), which TriPath claims is factual testimony as to equivalence, will be granted.[9]

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[8] TriPath, on the other hand, claims that it understood the order to strike only the response expert's testimony regarding the doctrine. To the contrary, the order is clear in barring the theory as such. *See* July 21, 2005 Order at 15. ("The DOE is such a fundamental form of infringement opinion, I will not permit that theory to be developed for the first time in 'response' expert reports.").

[9] Paragraphs 19-21 of the Reynolds Declaration *are* admissible to prove infringement of the means-plus-function claim 21. Literal infringement analysis of such claims requires equivalence analysis. Insofar as those paragraphs are offered to prove literal infringement, Cytyc's motion will be denied.

Cytyc had filed an earlier motion to exclude the entirety of

B. Theory of Contributory Infringement of Patent '377

TriPath argued in its moving papers that even if Cytyc has not itself infringed the '377 patent, it is a contributory infringer or an infringer by active inducement.[10] Cytyc seeks to strike this theory as waived because TriPath made no mention of it in its interrogatory responses or expert reports and Cytyc has had no fact or expert discovery on this issue.

It is true that TriPath pled contributory infringement in its counterclaim and its answer to Cytyc's complaint. TriPath made no explicit reference to the theory, however, after the pleadings until briefing the motion for summary judgment. In order to proceed on this claim, TriPath should have developed the theory during discovery and explicitly outlined a theory of contributory infringement in its expert reports. Introducing a new theory at this stage of litigation -- where factual and expert discovery has closed -- with no explanation for the delay is unacceptable. *See Powell v. Storz Opthalmics, Inc.*, 34 U.S.P.Q. 2d 1136, 1139-40 (M.D. Fla. 1994), *aff'd*, 53 F.3d 437 (Fed. Cir. 1995) (precluding patentee from introducing theory of

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the Reynolds' Expert Report. *See* Docket No. 142. That motion was superceded by Docket No. 214, Cytyc's motion to strike only portions of the report.

[10] Cytyc moved to strike the portions of Dr. Russ' Updated Report on the '377 patent that relate to the doctrine of equivalents. Cytyc's Motion to Exclude Portions of TriPath's Updated Expert Reports, Ex. 9 at 16 (Docket No. 142 at 2). As stated at the hearing on motions for summary judgment, TriPath has agreed to withdraw paragraph 9 and 12 insofar as they relate to a theory of infringement resting upon the doctrine of equivalents. *See* Tr. at 125-26.

infringement not disclosed during discovery after accused infringer had conducted discovery, prepared its case, and submitted dispositive motions).

TriPath should not be materially prejudiced by my decision on this issue. As stated below, I have denied Cytyc's motion for summary judgment with respect to literal infringement of the '377 patent; consequently, TriPath's direct infringement claim is alive and well. TriPath argues that pursuing a theory of contributory infringement will aid in emphasizing the fact that Cytyc's technology requires a human user. Concern for trial-presentation choreography, however, is not a valid reason for raising a new theory of contributory infringement post-discovery. TriPath will have an adequate opportunity at trial to provide evidence that Cytyc's technology prepares biological samples for human review.

C. TriPath's New Infringement Argument of Patent '969

Cytyc moves to strike as untimely TriPath's argument and supporting expert testimony that the TIS Review Scope (as opposed to the TIS Image Processor Subsystem) infringes claim 16 of the '969 Patent. Cytyc's motion to strike will be denied, but I will allow Cytyc to pursue additional discovery to rebut TriPath's argument.

TriPath first developed the Review Scope theory of infringement in expert report updates filed in March 2006. I had allowed the parties to submit the updated expert reports for the

sole purpose of reflecting the claim construction adopted in the November 2005 *Markman* Order. Cytyc claims that TriPath's new argument is not a response to the *Markman* order and that TriPath should have been able to make an argument that the Review Scope infringed claim 16 as early as August 2005 when the parties stipulated to a claim construction of the element "location information of interest" found in claim 16(b)(iii). Claiming undue prejudice, Cytyc has moved to strike the expert reports upon which TriPath relies for its argument that the Review Scope contains "means for automatically recording location information of interest" on the grounds that the argument should have been made in the initial round of expert reports. Specifically, Cytyc seeks to exclude ¶¶ 3, 5, and 9-12 of the Russ Updated Report. *See* Cytyc Motion to Strike, Ex. 4 (Docket #142).

Perhaps TriPath could have developed its infringement argument earlier than it did. But while the parties might have agreed to the relevant claim construction before the *Markman* hearing, they did so after the close of expert discovery. Thus, TriPath might not have been prompted to make the argument before the initial expert reports were due in March 2005. I do not conclude that TriPath could not or should not have made the argument in its initial expert report. But I also do not view the existence of the August 2005 stipulation, which was executed well after the last expert reports were circulated, as

determinative of whether TriPath knew enough to raise the argument in its initial expert report.

I will allow TriPath to pursue its infringement argument. The Review Scope infringement theory was introduced late but it was introduced well before the summary judgment briefing was due. Further, because it is not an entirely new fundamental theory of infringement, like the doctrine of equivalents, it should not widen the scope of discovery so much as to cause a delay in trial.

In summary, Cytyc's motion to strike the Review Scope infringement argument and supporting testimony will be denied. TriPath has agreed to withdraw paragraph 12 of the Russ updated expert report. Paragraphs 3, 5, and 9 are allowed. I will grant Cytyc's request for additional discovery to respond to the argument that the Review Scope infringes claim 16.

IV. '377 PATENT (RUTENBERG)

TriPath's '377 Patent describes technology that, like the TIS, screens and classifies biological material for the purpose of determining whether the material contains abnormal cells. Cytyc has filed a motion for summary judgment with respect to this patent on both noninfringement and patent invalidity. Specifically, Cytyc requests judgment as a matter of law that (1) its technology, TIS, does not infringe '377's independent claims 11 and 16 or dependent claims 13, 15, 17-18, 20, and 22-26, and (2) TriPath's patent was anticipated by two pieces of prior art,

both authored by Tanaka. TriPath has filed a cross motion for summary judgment on patent validity with respect to all the prior art at issue in the case.

A. Patent Infringement

Given some additional claim construction I provide in this section, I cannot find noninfringement as a matter of law with respect to independent claims 11 and 16 of the '377 patent.[11,12]

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[11] The text of claim 11 (with my emphasis added to highlight the major difference between Claims 11 and 16) is:

> A method for providing *interactive review* of objects in a specimen indicative of the highest likelihood of abnormality in the specimen, comprising the steps of:
> a) obtaining the specimen; and
> b) classifying the specimen to determine the likelihood that individual objects in the specimen have attributes of cell abnormality justifying further evaluation, said classifying including
>
> > I) assigning individual objects in the specimen a value according to the likelihood that an object has attributes of cell abnormality, and
> > ii) selecting location coordinates of one or more of the objects to provide for viewing and further classification by a human.

The text of Claim 16 (with my emphasis added) is:

> A method of providing *location-guided screening* of a specimen for objects in the specimen having a likelihood of cell abnormality, comprising the steps of:
>
> a) obtaining the specimen;
> b) classifying the specimen to determine the likelihood that individual objects in the specimen have attributes of cell abnormality justifying further evaluation, said classifying including
> > I) ranking objects in the specimen in an order according to the likelihood that an object has attributes of cell abnormality, and
> > ii) identifying locations of one or more of the objects

In order for a technology to infringe a patent, it must infringe every limitation embodied in the patented claim. *See* Section IIB, *supra*. Because accepting Cytyc's sole argument would exclude the preferred embodiment of the patented technology from the patent, I deny Cytyc's motion for summary judgment.

The single disputed issue for infringement regarding both claims 11 and 16 is whether Cytyc's technology "classifies *the specimen*," as opposed to "objects within the specimen."[13] There

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> to provide viewing and further classification by a human.

[12] Because infringement of a dependent claim cannot occur without infringement of the underlying independent claim, I first address the independent claims. *See Wahpeton Canvas Co., Inc. v. Frontier, Inc.*, 870 F.2d 1546, 1552 n.9 (Fed. Cir. 1989) ("One who does not infringe an independent claim cannot infringe a claim dependent on (and thus containing all the limitations of) that claim."). Claims 13 through 15 depend on claim 11, and include limitations on the types of cells to be screened and the system for assigning values to cells. Claims 17-20 and 22-26 depend on claim 16 and add limitations concerning the selection and presentation of objects of interest to a human, mapping the objects, and ranking them according to likelihood of abnormality and morphological features.

[13] Conceivably, one could instead frame the discussion around the definition of the term "specimen," which the parties have not defined. In argument, the parties seemed to refer to "specimen" as the entirety of a biological sample. One could imagine, however, that "specimen" refers to both the entirety of the sample *and* the cells or other objects within the sample. A specimen, in lay terms, is simply a portion of a larger whole. Both the slide (or possibly multiple slides) and the cells within the slide are part of the same, larger source (*e.g.* the cervical tissue).

TriPath's counsel stated during the summary judgment hearing that TriPath is not urging me to rephrase "classifying the specimen" to include "classifying objects within the specimen." At the same time, counsel argued that the patented technology classifies the specimen "by going through the entire specimen and screening out 99 percent of the objects," but without assigning

is no dispute that Cytyc's TIS meets the other limitations of the claims.[14] Cytyc argues, however, that the TIS does not "classify specimens" because the TIS never places *specimens* into one of two or more groups. *See* Markman Order at 66 (defining classifying as placing something into "one of two or more groups."). Instead, the TIS, Cytyc argues, merely facilitates human classification of the specimen by placing *objects within the specimen* into one of two or more groups. Docket No. 160 at 10. It is the human, not the machine, that Cytyc claims classifies the slide or entire specimen as normal or abnormal. Cytyc points to the following testimony by TriPath's technical expert:

Q: And so it is accurate to say that the TIS machine may

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the specimen to a group. *See* Tr. at 132; TriPath Slide titled "Rutenberg Classifiers: Primary, Secondary, Tertiary." Thus, it seems TriPath *is* arguing that I find that classifying the specimen includes classifying a subpart of or objects within the specimen.

Because the parties seem essentially to agree on the definition of "specimen," I will assume that it refers only to an entire sample of biological material and not the objects within the sample. This assumption should not be fatal to either side. The legal result is the same with respect to these claims regardless of whether I construe "specimen" as including "objects within the specimen" or construe the phrase "classifying the specimen" as including "classifying objects within the specimen."

[14]The parties agree that the TIS provides for interactive review, as in Claim 11, and location guided screening, as in Claim 16. The TIS "obtains the specimen," and screens the specimen "to determine the likelihood that individual objects in the specimen have attributes of cell abnormality justifying further evaluation." In both the patented technology and Cytyc's TIS, there are two levels of screening (primary and secondary) which determine the likelihood that individual objects have attributes of cell abnormality. The TIS assigns individual objects a value and ranks them according to their likely abnormality, and identifies locations of objects for further review.

> classify objects within a specimen but does not classify the specimen itself?
> A: Yes, that's correct.
> Q: And only the human being classifies the specimen?
> A: Yes.

Russ Dep. at 91 (Shannon Decl., Ex. 15).

The TIS does not infringe the '377 patent insofar as "classifying the specimen," on its face, does not include "classifying objects within the specimen." In the *Markman* order, I construed "classifying the specimen" to mean "classifying the specimen into one of two or more groups, including [by] primary and secondary classifiers, but not [by] a classifier, human or otherwise, that provides a final diagnosis." *See Markman* Order at 10-13.[15] Neither the parties nor I, however, addressed the

[15] TriPath contends that I have construed the term "classifying the specimen" incorrectly because I misconstrued the term "comprising" in Claims 11 and 16. In the *Markman* Order, I interpreted "comprising" as denoting a closed grouping. *See Markman* Order at 10-11. TriPath argues that the terms "comprising" and "including" are "open-ended," *i.e.*, that they both mean "including, *but not limited to.*" I must agree that under governing Federal Circuit law -- as opposed to classical grammatical usage convention -- "comprising" and "including" are open-ended. Cytyc does not dispute this contention. As the Federal Circuit has stated, "comprising" is "inclusive or open-ended and does not exclude additional, unrecited elements or method steps." *See CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1235 (Fed. Cir. 2005) ("A drafter uses the term 'comprising' to mean 'I claim at least what follows and potentially more.'") (quoting *Vehicular Tech. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1383 (Fed. Cir. 2000)); *see also Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1327 (Fed. Cir. 1999) (stating that "consisting of," on the other hand, indicates a closed grouping); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 688 (C.C.P.A. 1981). Thus, insofar as I have previously construed "comprising" as describing a closed set or a whole, TriPath has convinced me that I was incorrect and I will correct this aspect of the *Markman* order.

This correction, however, does not change my definition of "classifying the specimen" as used in claims 11 and 16. I will continue to construe "classifying the specimen" in those claims to exclude final classification. The resulting construction may be the result of an inartful draft in the patent claim, but it is the only way to make sense of language claiming a method "classifying the specimen to determine the likelihood that individual objects in the specimen have attributes of cell abnormality *justifying further evaluation*."

Because the change in the definition of "comprising" does not change my definition of "classifying the specimen," it is also immaterial to the dispute of whether Cytyc's TIS classifies the specimen as stated within claims 11 and 16. Cytyc's argument is that its technology does not perform one of the explicit steps within the claim, that is, "classifying the entire specimen for further evaluation." Thus, whether "comprising" is open-ended or not, the dispute is whether Cytyc's TIS performs that particular element.

Having corrected my claim construction to coincide with Federal Circuit case law, I am compelled to note in this connection that the Federal Circuit has chosen to become its own lexicographer for the word "comprise" by abandoning an ordinary, customary, and distinctive -- if frequently misunderstood -- meaning defended by usage experts.

The distinction is concisely stated in Gowers. "The difference between *comprise* and *include* is that *comprise* is correct when all the components are enumerated and *include* when only some of them are." Sir Ernest Gowers, *The Complete Plain Words* 215 (S. Greenbaum & J. Whitcut revision) (3d. ed. 1988).

Jacques Barzun has urged writers "to make the effort of coming to terms with *include, compose* and *comprise*." Jacques Barzun, *Simple & Direct: A Rhetoric for Writers* 128 (rev. ed. 1994). Barbara Wallraff explains that "[t]he reason *comprise* is confusing to many people is the same reason that it's useful: It doesn't work the same way as similar words." Barbara Wallraff, *Word Court* 176 (2000).

Among those concerned with maintaining meaningful linguistic distinctions, the difference between "comprise" and "include" continues to be observed.

The preeminent Twentieth Century newspaper copy editor explained that "[c]omprise has the meaning of contain, embrace, include and comprehend . . . The whole *comprises* the parts, not the reverse." Theodore M. Bernstein, *The Careful Writer: A Modern Guide to English Usage* 113 (1965). He further observed that "[t]he word *include*, however, usually suggests that the component items are not being mentioned in their entirety. If all are being mentioned it would be better to write 'The seven

definition of the term "specimen" or whether "classifying the specimen" could include classifying objects within the specimen. Cytyc suggests that classifying the specimen involves assigning the entire specimen to one of two or more groups, whatever the specimen consists of. That reading would exclude Cytyc's technology because the TIS primary and secondary screens do not assign the entire specimen into one of two or more groups "for further classification." but rather, do so only for objects or cells within a specimen.

But under Cytyc's reading, the preferred embodiment of the patented technology would also not "infringe" the asserted claims. In the preferred embodiment, as TriPath points out, the first two screenings identify only objects within the specimen as

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were . . .'; or, if there is an irresistible urge for a fancy word, to use *comprised." Id.* at 228.

Similarly, a journeyman book of American usage cautions writers to "be careful to use *include* only of incomplete lists: A baseball team is made up of nine players. It *includes* a pitcher, a catcher, and four infielders. It is *composed* of these, plus three outfielders. (And the team *comprises* these nine players; they *compose* the team.)" Kenneth G. Wilson, *The Columbia Guide to Standard American Usage* 106 (1993).

Of course the distinctiveness of words in common and ordinary meaning can be eroded when those bodies charged with superintending language, such as the Federal Circuit, neglect the distinctions. Thus the former editor of the Oxford English dictionaries has reported from the field that "*[c]omprise* is . . competing with *include*". *The New Fowler's Modern English Usage* 387 (3d ed. 1996). Nevertheless in this competition he finds that the differences still remain: "[w]hen two words such as *include* and *comprise* have roughly the same meaning, examination will generally reveal a distinction; and the distinction between the present two seems to be that *comprise* is appropriate when the content of the whole is in question, and *include* only when the admission or presence of an item is in question." *Id.*

normal or abnormal without classifying the specimen as a whole. The '377 specification seems to use "classifying the specimen" interchangeably with "classifying portions of the specimen." *See, e.g.*, column 2, lines 31 - 37 ("[T]he invention includes an initial classifier . . . to *classify a cytological specimen* and a subsequent classifier . . . to classify those *portions of the cytological specimen* selected by the initial classifier for subsequent classification."). It seems clear, as well, that the primary and secondary classifiers that Rutenberg describes classify only objects within one biological sample. *See, e.g.*, column 17, lines 34-52:

> Fig. 5 shows the screening of a typical Pap smear which contains approximately 100,000 benign cells and other objects. Through erosion/dilation and IDO filters, the primary classifier 400 will filter out 99% of these objects, passing approximately 1,000 objects to the secondary classifier 420. Classifier 420 . . . in turn filters out 80% of these 1,000 objects, passing the images of approximately 200 residual objects deemed to be the most suspect of pathology to the output monitor for tertiary human inspection.

If a Pap smear is the same as a "specimen," then the '377 specification clearly calls for a method of screening out objects within that specimen. In other words, because "classifying the specimen," according to my construction, must refer to the classification by only the primary and secondary classifiers, "classifying the *entire* specimen" is something that neither Cytyc's TIS nor '377's methods 11 and 16 perform.

To avoid the untenable result that the patent claim excludes

the preferred embodiment of the patented technology, I must construe "classifying the specimen" to include classifying objects within a specimen in an overall process falling short of classifying the entire specimen.[16] Under this construction, Cytyc's TIS "classifies the specimen . . . for further review by a human" insofar as it screens objects within the specimen and assigns them to groups. Cytyc does not dispute that its technology classifies objects within a specimen. Thus, Cytyc's current motion for summary judgment[17] is denied with respect to the asserted claims.[18]

B. Patent Validity

Cytyc has moved for summary judgment asserting that claims of the '377 patent are invalid as anticipated by prior art. Specifically, Cytyc claims that over a year before the '377

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[16] Cytyc argues that if the '377 specification describes something other than what is claimed then the patent is invalid under 35 U.S.C. § 112. Here, however, the claim construction does not absolutely exclude the technology described in the specification, because whether "classifying the specimen" can include "classifying portions of the specimen" was not previously determined.

[17] Given this construction, TriPath may wish to reframe a motion for judgment on infringement. This would provide the parties an opportunity to contemplate and respond to my revised construction.

[18] Cytyc's motion is denied as to both the asserted independent and the asserted dependent claims of claims 11 and 16. Cytyc's sole argument that the TIS does not infringe on the dependent claims is that the TIS does not infringe on the independent claims. Thus, having denied summary judgment on the independent claims, I must deny it with respect to the dependent claims as well.

patent application was filed, Dr. Noboru Tanaka published two articles describing the CYBEST Model 4, an automated cytological screening system (herein referred to as Tanaka I and II).[19] Dr. Tanaka's articles, it contends, disclose each element of and therefore anticipate the asserted claims of the '377 patent pursuant to 35 U.S.C. §102.

TriPath has, in turn, filed a cross-motion for summary judgment, seeking a declaration that its patent was not anticipated by Tanaka I or Tanaka II.[20] Additionally, TriPath seeks a declaration of nonanticipation with respect to four additional references: (1) two articles describing a cervical specimen screening device developed by O.A.N. Husain in the United Kingdom (herein referred to as Husain II and III);[21] (2) an article by S. Donald Greenberg describing a system for

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[19] The full references are: Tanaka, *et. al*, "Automated Cytologic Screening System (CYBEST model 4): An Integrated Image Cytometry System," *Applied Optics*, Vol. 26, No. 16, pp. 3301-07, August 1987 ("Tanaka I") (Shannon Decl., Ex. 5); Tanaka, *et. al*, "CYBEST Model 4 Automated Cytologic Screening System for Uterine Cancer Utilizing Image Analysis Processing," *Analytical and Quantative Cytology and Histology*, Vol. 9, No. 5, pp. 449-454, October 1987 ("Tanaka II") (Shannon Decl., Ex. 6).

[20] Cytyc has also pled obviousness with respect to the references that are the subject of TriPath's nonanticipation motion pursuant to 35 U.S.C. §103. Docket No. 191 at 3. Neither party has filed a motion for summary judgment on the obviousness issue.

[21] The full references are: Husain, *et. al*., "Development Trials of the Cervifip Automated Cervical Cell Scanner," *Clinical Cytometry and Histometry*, pp. 352-55, 1987("Husain II"); Husain & Watts, "Computerised Cell Scanners," *Phys. Bul.* 28, pp. 198-200, 1988("Husain III").

analyzing abnormalities in lung cells ("Greenberg");[22] and (3) a cervical specimen screening device developed by Cytyc in the late 1980s known as the CDS-1000.[23]

1. Anticipation of the '377 Patent by Tanaka I and II

Cytyc contends that the Tanaka references anticipate each element of the asserted claims. TriPath argues that the Tanaka references are nonanticipatory because they fail to disclose the following six claim limitations: (1) "interactive review" (claim 11); (2) "classifying the specimen" (claims 11 and 16); (3) locating and identifying objects for "further classification by a human" (claims 11 and 16); (4) "assigning a value on a scale" (claim 14); (5) "location guided screening" (claim 16); and (6) "ranking objects in the specimen" (claim 16). For the reasons below, I will deny both parties' motions for summary judgment with respect to anticipation of claims 11 and 16 of the '377 patent because there is a disputed issue of whether Tanaka's CYBEST Model 4 discloses a method for "further classification by a human."

a. Tanaka I and II Technology

Tanaka I and II describe the CYBEST Model 4, an automated

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[22] The full reference is: Greenberg, *et. al.*, "Application of Cell-Image Analysis to the Diagnosis of Cellular Atypias in Sputum: A Review," *Diagnostic Cytopathology*, Vol. 2, No. 2, pp. 168-73, April - June 1986 ("Greenberg").

[23] A reference describing the CDS-1000 is: "The ThinPrep Processor and the CDS-1000 Cytology WorkStation," Automated Cervical Cancer Screening Second Annual International Symposium, October 29-31, 1992, Atlanta, Georgia, pp. 1969-1991 ("CDS-1000 Article").

cytologic screening system for uterine cancer that "utilize[s] image analysis technology for the automated prescreening of cervical cytology specimens." Tanaka II at 449. After 14 years of research, Dr. Noboru Tanaka developed the CYBEST Model 4 in 1981. I note at the outset that the Tanaka references were not listed as cited references on the face of the '377 patent, and there is no evidence that the Patent and Trademark Office considered Tanaka I or II during the prosecution of '377. The PTO did, however, consider an older Tanaka model, the CYBEST Model 3, and determined that it did not anticipate TriPath's claimed methods.

The CYBEST Model 4 system scanned specimen slides to obtain digital images of individual cells and cell specimens. *Id.* at 451. It then analyzed the cells using five parameters: nuclear size, nuclear-cytoplasmic ratio, nuclear optical density, nuclear shape, and chromatin pattern. *Id.* These parameters were weighted according to their importance and used to generate an "atypicality grade" for individual cells. *Id.* at 452. Each cell was assigned one of 19 rankings between +1 and -1, with +1 the highest grade (definitely malignant) and -1 the lowest (definitely benign). *Id.* The atypicality grades for each cell were accumulated into a ranking for the overall specimen slide, on the same 19-point scale. *Id.*

As an "optional feature," the CYBEST Model 4 allowed for post-screening human review of the ten cells with the highest

atypicality rank. *Id.* This "10-cell system" displayed all of the measurement data, the atypicality grade, and the final specimen assessment (normal, suspicious, or reject) on the screen for the reviewer. *Id.* The primary purpose of this feature was to "confirm[] the machine assessment by direct manual optical observation and for evaluation of the accuracy of the automated system." *Id.*

b. Disclosure of "Interactive Review" by Tanaka I and II (Claim 11)

For the reasons stated below, I conclude that Tanaka I and II disclosed a method providing for "interactive review." Before reaching the question of disclosure, however, I must address: (1) the definition of interactive review, and (2) whether the term "interactive review" limits claim 11 of the '377 patent.

i. Definition of "Interactive Review"

As discussed below, I construe "interactive review" as used in claim 11 to mean "review by a human of the results from an initial classification." TriPath defines the term as "subsequent human examination of selected objects within a specimen via interaction with a machine, such as by a series of human commands and associated machine responses." Docket No. 218 at 2. Cytyc proposes no definition, but it insists that the term does not incorporate human classification of a specimen. That question was resolved, it claims, by the *Markman* Order, which excluded human review from the definition of "classifying the specimen."

A fully-automated system cannot infringe the asserted claims

of the Rutenberg '377 patent. For clarity, I should briefly rehearse the conclusions of the *Markman* order. Although I did not explicitly state it then, I construe claims 11 and 16 to patent a method that must include *some* further human classification of the specimen. *See* claims 11(b)(ii); 16(b)(ii) ("further classification *by a human*"). Nonetheless, I concluded in the *Markman* hearing that a machine, rather than a human, might perform the *final* classification in the technology that the '377 patent claims. That conclusion is consistent with the fact that claims 11 and 16 contemplate at least some -- not necessarily final -- human classification.

With this in mind, I will construe "interactive review" as stated in the '377 patent as "review by a human of the results from an initial classification." The word "interactive" in common usage suggests influence or reciprocity between two different entities. *See Webster's Third New International Dictionary* (1986). Given the language in the claim stating that the method provides for "interactive review . . . including identifying objects . . . for further classification by a human," at least one of the interacting entities should be a human.[24]

The term "review" denotes an examination. Technically, a

[24] Counsel for TriPath asserted during the summary judgment hearing that "to prove infringement of the claim, you do not have to prove human use." *See* Tr. at 134 (LaPorte statement). I interpret this statement to mean *not* that a fully-automated system can infringe claims 11 and 16, but instead that TriPath need prove only that the infringing technology *prepare* the specimen for some further human classification.

review is the examination of something that has already been examined in one form or another. The common usage of the term may sometimes be broader; some portion of the population will often use the term "review" to denote an initial examination. In the context of this claim, however, there is no dispute that the interactive review occurs subsequent to an initial examination by a machine. Thus, I adopt a modified version of TriPath's proposed definition for "interactive review": examination by a human of the results of an initial examination.

Contrary to Cytyc's argument, the definition of "interactive review" is not limited by the claimed steps of claims 11 and 16. Claims 11 and 16 describe methods (including classifying the specimen) that merely "provide" for further interactive review. Claim 11 reads, "A method for providing interactive review of objects in a specimen indicative of the highest likelihood of abnormality. . . comprising . . . obtaining the specimen" and "classifying the specimen." Thus, the definition of "classifying the specimen," which here is only a method of preparing a slide for interactive review, is not relevant to the definition of "interactive review."

ii. "Interactive Review" as Limiting Claim 11

I also construe the term "interactive review," which occurs in the preamble of claim 11, as claim-limiting. A preamble "limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Marketing Int'l, Inc. v. Coolsavings.com,*

Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. Hewlett Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). "Conversely, a preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use of the invention.'" *Id.* (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1977)).

I concur with Cytyc that "interactive review" is an introductory descriptive term that does not add meaning to the body of claim 11. As stated above, the claimed method only prepares the specimen for interactive review. Ordinarily, where the preamble describes the purpose of the method, as it does here, it is not considered limiting. *See Catalina Marketing*, 289 F.3d at 809.

There is, however, an exception to the life-and-vitality test when the applicant has explicitly relied upon a feature in the preamble during prosecution to distinguish it from prior art. *Id.* at 808 ("[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention."). TriPath argues that the exception applies here, and I agree.

The evidence shows that the patentee attempted to distinguish his invention from fully automated systems during the prosecution process. *See* Amendment at 8 (March 14, 1994) (Daniel

Decl. Ex. 13, Tab 30). The premise of the '377 invention, as explained by the applicant, is that humans are more adept than machines at visual recognition and classification. *Id.* at 6. The purpose of the method is not to analyze or categorize a specimen completely, but merely to save the cytotechnologist's time in the overall analysis. *Id.* Because the claim contemplates some manual review, the applicant described his invention as "semi-automated," specifically making use of the term "interactive." *Id.* at 7. The applicant claimed that this "interactive" feature of his invention was contrary to the trend of prior art classifiers, which sought to remove the human factor from the classification process altogether. *Id.*

The applicant relied "clearly and unmistakably" upon the interactive nature of the invention to distinguish it over the prior art. *See Catalina Marketing*, 289 F.3d at 809. Thus, "interactive review" is a claim limitation, and it must be present in the Tanaka references in order to prove anticipation.

iii. Disclosure of "Interactive Review" (Claim 11)

Given the above construction, I find the Tanaka references disclose a method providing for "interactive review." A claim is anticipated "if each and every limitation is found either expressly or inherently in a single prior art reference." *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1381 (Fed. Cir. 2005). The Tanaka references describe a system that allows for some form of human review of the initial classification. The 10-cell system, although optional, provides humans the

opportunity to examine a specimen. This optional human interaction after initial examination by a machine anticipates the "method providing for interactive review" in claim 11. *See Upsher-Smith Laboratories, Inc. v. Pamlab, LLC*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (stating that technology that "optionally includes" an item anticipates a claim that expressly includes it).

c. Disclosure of "Classifing the Specimen . . ." (Claims 11 and 16)

There is a genuine dispute of fact as to whether Tanaka I and II disclose the methods of Claims 11 and 16. TriPath argues that the CYBEST Model 4, unlike their claimed method, is a fully-automated system that produces a final diagnosis at the completion of the screening process. Any additional human review, it contends, is merely an optional quality control feature unrelated to classification. TriPath essentially argues that the CYBEST model 4 does not anticipate "classifying a specimen . . . for . . . further classification by a human." I agree the references are ambiguous as to this issue. Cytyc argues that Tanaka's 10-cell system provides a human operator the opportunity to retain or correct the initial classification, and consequently, in cases where the human reviews the results, the human does make the final diagnosis.

I must emphasize that Tanaka I and II do not need to disclose the human as the *final* classifier in order to anticipate

TriPath's technology. As discussed in the previous section addressing "interactive review," TriPath's technology does not require a human as the final classifier. It is true that in the preferred embodiment described in the '377 specification, the human is the final classifier. It is also true that claims 11 and 16 require *some* form of human classification of the specimen. The final classification, however, as the specification implies, could be automated. Thus, in order for Tanaka I and II to disclose "classifying the specimen," there need only be some form of "further classification by a human."

Tanaka I and II disclose a system that provides fully-automated classification with the option of subsequent human review of the 10 most atypical cells. The question is whether the optional human review includes any *classification* of the specimen. The description of the 10-cell system explains that the purpose of the human review as a "useful . . . confirmation of the machine assessment" and an opportunity to evaluate "the accuracy of the automated system." The words "assessment," "accuracy," and "automated" as they are used in Tanaka II could support an inference that the human's role is solely that of general quality control to confirm that the machine is not broken, *i.e.*, that the human would never engage in "classification." In other words, it is unclear from the Tanaka literature whether, during the 10-cell review, the human assigns the specimen or portions of the specimen into one of two or more groups.

TriPath points to considerable evidence that Tanaka discloses a fully-automated process, but this evidence does not exclude the possibility of optional human classification. It is true that Tanaka's articles refer to the invention as an "automated" -- as opposed to "semi-automated" -- process.[25] It is also true that the Tanaka computer assigns each specimen a "final assessment" of "normal," "suspicious," or "rejected." Contrast this to the '377 patent, which does not label the entire specimens at all, but leaves that diagnostic function to the (possibly-human) reviewer in the tertiary classification.

But the Tanaka references also contain language supporting the inference that it has disclosed a semi-automated system. First, the Tanaka I abstract describes the invention as an automated "prescreening" process. One could similarly describe TriPath's methods claimed in 11 and 16 as embodying a fully-automated pre-screening process that allows a human to perform additional classification. Second and more importantly, Tanaka's 10-cell system, read literally, is a form of human review or

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[25] TriPath's '377 specification also describes its technology as "automated," though it states that it uses the term to refer to the fact that "at least part of the process is performed by a machine." One could infer from this statement that the '377 patent claims semi-automated *and* fully-automated technologies (*i.e.*, of which at least part, if not all, is automated). Neither claim 11 nor claim 16, however, claims a fully-automated system, because they both prepare slides for some form of human classification. Thus, insofar as Tanaka I and II disclose fully-automated systems, they do not anticipate claims 11 and 16.

examination of the most atypical specimens. It allows a human to analyze the specimen, and perhaps, although it is not quite clear, override the classification provided by the machine, allowing for a "super-final" classification by a human. Finally, the description of the CYBEST system in the Husain III article suggests that human review is an integral part of the CYBEST invention: "[The CYBEST] uses an exclusive algorithm for clusters and overlaps and produces an atypicality index or ranking of abnormal signals which are then submitted for operator review." Husain III at 200. This evidence is sufficient to support an inference that Tanaka discloses a method that "classifies the specimen . . . for further classification by a human."

I must deny both parties' motions for summary judgment on the issue of anticipation of claim 11 and 16 (and, *mutatis mutandis*, on their dependent claims). The question for the jury will be whether Tanaka I or II disclosed a method providing for subsequent human review that amounts to "classification," or whether the review performed by the human after looking at the 10-cell system falls short of assigning the specimen or portions of the specimen into one of two or more groups.

d. Disclosure of "Assigning a Value on a Scale" (Claim 14)

Tanaka I and II disclose a method "assigning a value on a scale" as claimed in claim 14 of the '377 patent. Claim 14 depends on claim 11 and adds the limitation of "assigning value

on a scale between a first output value associated with a first condition and a second output value associated with a second condition." The CYBEST model 4 classifies cells by assigning them one of 19 values between -1 and +1, with +1 indicating "definitely malignant" and -1 indicating "definitely benign." Tanaka I at 3302. Thus, the Tanaka technology assigns a value on a scale between a first output value (-1) associated with a first condition (benign) and a second output value (+1) associated with a second condition (malignant).

TriPath argues that Tanaka I and II do not assign values "on a scale" because the scale is not continuous. Claim 14, however, does not require that the scale be continuous, and I will not construe it as such. Relatedly, TriPath argues that because the CYBEST assigns only one of 19 values between -1 and +1 to each cell, allowing for the possibility that two cells could share the same value, it does not amount to assigning values on a scale. This argument also fails. TriPath's patent does not require that each object have a unique value.[26]

e. Disclosure of "Location Guided Screening" (Claim 16)

The parties have not agreed to nor proposed definitions for "location-guided screening"; nor have they asked me to construe the term. Though "location-guided screening" could be a self-

[26] The Tanaka references may similarly be read to disclose dependent claim 15, which reads "[t]he method according to claim 14, wherein the first condition is benign and the second condition is non-benign."

explanatory term of common usage, it is possibly a technical term. Additionally, the parties have not provided argument beyond bare assertion about whether the term, located in the preamble of claim 16, is claim-limiting. Consequently, I cannot determine whether the Tanaka references anticipate this element for purposes of summary judgment.

f. Disclosure of "Ranking Objects in the Specimen"

There is no doubt that Tanaka I and II disclose a method that "ranks objects in a specimen in an order according to the likelihood that an object has attributes of cell abnomality." To quote from the Tanka I article: "Ten cells can be called out . . . in the order of highest atypical rank." Tanaka I at 3305; *see also* Figure 11 (showing the 10-cell ranking of "most malignant cell review").

TriPath's various arguments that Tanaka I and II fail to disclose a method of ranking are not persuasive. TriPath first argues that Cybest Model 4 does not rank objects because after it assigns values it does not place them in order. First, Figure 11 in the Tanaka article shows a ranking of the ten most atypical cells in order of their atypicality. Perhaps TriPath has ignored the 10-cell system because it is an "optional" feature, but the case law has established that optional facets of a technology are fully capable of anticipating TriPath's claims. *See Upsher-Smith*, 412 F.3d at 1322.

Second, assigning values to objects on a numerical scale is equivalent to putting them in order. The values themselves certainly have an order, and assigning objects to values with an inherent order is equivalent to ranking. The parties previously agreed that "ranking" means "placing objects in a row, or order in such a manner that the first ranked object is the one with the greatest probability of exhibiting a particular characteristic, and the second ranked object is the object with the second greatest probability of exhibiting a particular characteristic, etc." *Markman* Order at 68. Under my construction and this stipulated definition, the Tanaka 10-cell output anticipates a method of ranking because it prints out the 10 most malignant cells "in order."

There is no evidence for TriPath's assertion that the 10-cell system's ranking of "Most Malignant Cells" was not actually a ranking of the most malignant cells. TriPath asserted at hearing that the label on Tanaka's Figure 11 is inaccurate and that the Tanaka technology disclosed only a method for ranking by one parameter (the N/C ratio), rather than by atypicality. TriPath argues that, as a result, the disclosure of a ranking method is at least ambiguous. I do not find ambiguity. Tanaka II states specifically that the 10-cell system can provide a print out of the "ten most atypical cells in a specimen." Tanaka II at Figure 7. An example of this list is presented in Figure 11 of Tanaka I and labeled "10 Most Malignant Cells." The

literature discloses that it determines atypicality by using a weighted average of five different parameters, only one of which is the N/C parameter. *See* Tanaka I at Figure 5. Given the formula for the weighted average, it is not surprising that the ranking of the cells in Figure 11 happens to track the ranking of the N/C ratio. I have no reason to doubt the accuracy of the Tanaka figures and assertions, and TriPath has submitted no evidence or expert testimony regarding the alleged ambiguity of the references.

g. Conclusion

In sum, although Tanaka I and II disclose the elements of "interactive review," "assigning a value," and "ranking," there is a genuine dispute of fact as to whether it also includes "classifying the specimen . . . for further classification by a human." In addition, given the lack of briefing, whether "location-guided screening" is a claim limitation, how it should be construed, and whether it is anticipated are still open to debate. Consequently, both parties' motions for summary judgment will be denied on the question of anticipation by the Tanaka references.

2. Anticipation of the '377 Patent by Husain II and III

I find that neither Husain II or III anticipate the '377 patent, for reasons discussed below.

a. Husain II

Husain II discusses the development of a semi-automated screening device. The device operates by scanning a prescribed region of a slide and registering the location of suspicious cells. Husain II at 353. These cells are then recalled under computer control for operator viewing and classification. *Id.* The machine identifies suspicious cells by calculating the area, integrated optical density, aspect ratio, circularity, and convexity or concavity of the outline of the objects. *Id.* Objects with an optical density greater than 1.8 times the mode are considered "suspicious." *Id.* The automatic scanning continues until the device identifies 100 suspicious cells or scans the entire area. *Id.* The human operator than classifies the selected cells as "abnormal," "inflammatory," "normal," or "artifact." *Id.*

Husain II is not anticipatory because it does not disclose an enabling method for ranking cells according to their abnormality. The authors state that they "are currently investigating the use of ranking the abnormal susps [sic] detected in conjunction with high resolution texture analysis," Husain II at 354, but they stop there. This vague suggestion does not constitute an enabling disclosure for purposes of 35 U.S.C. §102(b). *See Motorola, Inc. v. Interdigital Technology Corp.*, 121 F.3d 1461, 1471 (Fed. Cir. 1997) (stating that prior art must be enabling to anticipate).

b. Husain III

Husain III is an article describing in very general terms the operation of the Cytoscan automated cervical cancer screening system that was under development at the Charing Cross Hospital in England in the late 1980s. The Cytoscan scanned slides and presented "a hierarchic classification of cells and artefacts" based on cell size, shape, integrated optical density, and nuclear mass. Husain III at 199. A human operator then reviewed the suspect objects. *Id.*

Husain III is also not sufficiently enabling to be anticipatory. The article mentions that "suspicious signals" are identified by the machine and "ranked in order of severity for operator review." *Id.* at 200. These vague references, however, are the only indication of any ranking feature. It does not disclose whether those suspect cells are assigned values and ranked along a numeric scale and whether they are located or mapped. There is also no evidence that the disclosed machine classifies the specimen or reviews a preset number of cells, as disclosed in Husain II. Without more information, Husain III cannot be an enabling disclosure that anticipates the asserted claims.

c. Conclusion

In sum, there is not enough evidence to support an inference

that either Husain II or III is anticipatory. Consequently, I grant TriPath's motion for summary judgment of nonanticipation with respect to these references.

3. Anticipation of the '377 Patent by Greenberg

The Greenberg reference does not anticipate TriPath's claims because it discloses a fully-automated system. Greenberg discloses a system for assigning numerical values to the various stages of lung cancer cells. The cells are scanned and classified by computer, using the Atypia Status Index (ASI) developed by the authors. Greenberg at 171. The ASI is an objective measurement of atypicality scaled from minima of 0.5 (least abnormal) to 4.5 (malignant). *Id.* Depending on which ASI value a cell is assigned, it can be classified into one of five diagnoses: squamous metaplasia (0.5 - 1.4), mild atypia (1.5 - 2.4), moderate atypia (2.5 - 3.4), severe atypia (3.5 - 4.4), and carcinoma (4.5 - 5.5). *Id.* The ASI is computed mathematically by using a combination of parameters derived from analysis of fourteen features of the nucleus and cytoplasm of the cells. *Id.* at 171-72. It is designed to "identify, classify, and quantify the degree of cellular atypia." *Id.* at 171.

The Greenberg technology is fully-automated and thus nonanticipatory. Some human classification is, as discussed above, an essential part of Rutenberg technology. A fully-automated technology allowing for no human review cannot infringe

or anticipate TriPath's claims. The ASI ranking provides a preliminary measure of atypicality, but then it places the cells into one of five final categories with diagnostic significance. No subsequent human review is contemplated and thus the technology cannot anticipate the Rutenberg methods.

Cytyc argues that the fact that the authors of the Greenberg study conducted "visual inspection of slides" to compare the machine results with clinical diagnoses in Greenberg is sufficient to disclose human classification. I disagree. The fact that the authors of the article took steps to confirm that their technology produced results similar to clinical evaluation does not support an inference that human review was disclosed as a part of the classification process. Consequently, TriPath's motion for summary judgment of nonanticipation with respect to this reference is granted.

4. Anticipation of the '377 Patent by CDS-1000

I will grant TriPath's motion for summary judgment with respect to nonanticipation by CDS-1000 because the CDS-1000 does not qualify as prior art. First, the CDS-1000 system is not prior art under 35 U.S.C. §§ 102(a) or (b). In order to anticipate a patent under those sections, the technology must be known, used, or described in a printed publication before the applicant invented the anticipated technology, or publicly displayed more than one year before the filing of the anticipated

patent. 35 U.S.C. §§ 102(a), 102(b). The CDS-1000 was a computer screening system designed by Cytyc that analyzed slides of cervical tissue. CDS-1000 Article at 1971. There is no evidence that the technology was documented in a published article nor publicly displayed before the effective filing date of the '377, which was October 11, 1989.[27]

Second, the CDS-1000 is not prior art under § 102(g)(2). Section 102(g)(2) invalidates a patent if "before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." In proving anticipation by clear and convincing evidence, oral testimony of priority in invention under § 102(g) must be corroborated by other evidence, such as documents or patents. *See Finnigan Corp. v. Int'l Trade Commission*, 180 F.3d 1354, 1368-69 (Fed. Cir. 1999) ("[T]he case law is unequivocal that an inventor's testimony respecting facts surrounding a claim of derivation or priority of invention cannot, standing alone, rise to the level of clear and convincing proof."). Although Cytyc

[27] Cytyc claims that the CDS-1000 was shown publicly at a meeting of the American Society of Clinical Pathologists in Dallas, Texas, in October of 1990. This public display is after the filing date, and is therefore irrelevant for purposes of §102(b). David J. Zahniser, Ph.D., who was a former employee of Cytyc, testified that the CDS-1000 was described to potential customers sometime prior to the fall of 1990. He made no assertion, however, that the system was "displayed," nor that he made public the description of the technology before the fall of *1988*, which is the relevant priority date.

has submitted oral testimony by Dr. Zahniser that an inventor conceived of the CDS-1000 and diligently began reducing it to practice as early as April 1987, it provides no documentary or other evidence corroborating the date of conception of the technology. Thus, Cytyc's evidence does not meet the Federal Circuit's evidentiary standard for proof of anticipation under § 102(g) and TriPath's motion for summary judgment of nonanticipation with respect to this reference will be granted.

V. '182 PATENT (LUCK)

The '182 patent claims methods and an apparatus for automating the classification of biological samples that are intended to improve upon the classification method of the '377 patent. The parties have filed cross motions for summary judgment on the issues of infringement and patent validity.

A. Infringement

At the hearing on motions for summary judgment in this case, TriPath indicated that it would not be pursuing a claim of literal infringement against Cytyc for the Luck '182 patent. Instead, TriPath has asserted that the TIS infringes independent claims 1 and 21 and dependent claims 2, 3, and 4 of the '182 patent under the doctrine of equivalents. For reasons explained in Section III.A. above, TriPath is foreclosed from pursuing a theory of infringement based upon the doctrine of equivalents. Thus, I will grant Cytyc's motion for summary judgment as a

matter of law with respect to infringement of the '182 patent.

B. Anticipation of the '182 Patent by Tanaka I and II

For the reasons stated below, I will grant TriPath's motion for summary judgment and deny Cytyc's motion with respect to anticipation of the '182 patent. Cytyc has filed a motion for summary judgment on whether Tanaka I and II, discussed above in Section IV.B.1. with respect to the '377 patent, anticipate claims 1 - 4 and 21 of the '182 patent.[28,29] TriPath has moved for

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[28] The full text of the claim 1 is:

> A method of classifying objects in a cytological specimen, comprising the steps of:
>
> a) obtaining a first image of at least part of such cytological specimen;
>
> b) classifying objects in such first image on the basis of a predetermined criteria;
>
> c) selecting at least one object for display based on said classifying;
>
> d) obtaining a second image of at least part of such cytological specimen containing said at least one selected object;
>
> e) displaying at least part of such second image to produce a visual display of said at least one selected object.

Dependent claims 3, and 4 add the limitations related to resolution, classification, and the number of objects in the display:

> 3. The method of claim 1, including the step of further classifying such objects in such visual display.
>
> 4. The method of claim 1 wherein such visual display represents plural objects.

Claim 21 is a means-plus-function claim covers an apparatus, as opposed to a method. It provides:

> An apparatus for classifying objects in a cytological specimen, comprising:
>
> means for obtaining a first image of at least part of

summary judgment of nonanticipation, seeking a determination that neither the Tanaka references nor certain other prior art references anticipate.[30] Cytyc has conceded that, in light of

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> such cytological specimen;
> means for classifying objects in such first image on the basis of a predetermined criteria;
> means for selecting at least one object for display based on classification performed by said means for classifying;
> means for obtaining a second image of such cytological specimen containing said at least one selected object; and
> means for displaying at least part of such second image to produce a visual display of said at least one selected object.

[29] Cytyc does not seem to dispute that claim 2 is nonanticipated. Claim 2 is dependent on claim 1 and reads, "The method of claim 1, wherein such first image is of a lower resolution than such second image."

[30] The other references include: Husain, *et. al.*, "Automation in Cervical Cancer Screening -- Part 1: Fixed Cell Scanning Systems," *Biomedical Engineering*, pp. 161-66 (1976) ("Husain I") (Daniel Ex. 39); Husain, *et. al.*, "Development Trials of the Cervifip Automated Cervical Cell Scanner," *Clinical Cytometry and Histometry*, pp. 352-55, 1987("Husain II")(Daniel Ex. 40), Husain & Watts, "Computerised Cell Scanners," *Phys. Bul.* 28, pp. 198-200, 1988("Husain III")(Daniel Ex. 41); Norgern, et. al., "Leukocyte Image Analysis in the diff3 System," *Pattern Recognition*, Vol. 13, No. 4, pp. 299-314 ("Diff3 System") (Daniel Ex. 43); Aagarwal, *et. al.*, "A Multi-Spectral Approach for Scene Analysis of Cervical Cytology Smears," *Journal of Histochemistry and Cytochemistry*, Vol. 25, No. 7, pp. 668-80 (1977)(Daniel Ex. 44); Ploem, *et. al*, "An Automated Microscope for Quantative Cytology Combining Television Image Analysis and Stage Scanning Microphotometry," *Journal of Histochemistry and Cytochemistry*, Vol. 27, No. 1, pp. 136-143 (1979) (Daniel Ex. 45); Al & Ploem, "Detection of Suspicious Cells and Rejection of Artifacts in Cervical Cytology Using the Leyden Television Analysis System, *Journal of Histochemistry and Cytochemistry*, Vol. 27, No. 1, pp. 629-34 (1979) (Daniel Ex. 46); Driel-Kulker & Ploem, "The Use of LEYTAS in Analytical and Quantitative Cytology," *IEEE Transactions on Biomedical Engineering,* Vol. BME-29, No. 2 (Feb. 1992) (Daniel Ex. 47).

the *Markman* Order, all the references except for Tanaka I and II do not anticipate.

I find the Tanaka references also do not anticipate the independent claims of the '182 patent. Tanaka I and II discuss the CYBEST Model 4 automated cytologic screening system. *See* section IV(B)(1)(a), *supra*. The disputed issue is whether the Tanaka technology obtains and displays a second image. As described below, the references indicate that the CYBEST Model 4 obtains only one image, even with the use of the optional 10-cell system, and thus it does not anticipate the '182 patent.

There is no dispute that Tanaka I and II disclose the first three steps of claim 1. Claim 1 of the '182 patent requires five enumerated steps to occur, or in the case of claim 21, means to be present, as part of the method of classifying: (1) obtaining a first image; (2) classifying objects in such first image; (3) selecting at least one object for display; (4) obtaining a second image; and (5) displaying that second image.

With respect to steps (4) and (5) of claim 1, the parties debate whether the optional 10-cell system is part of the classification process.[31] As discussed above, the 10-cell

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[31] TriPath also argues that the Tanaka references are not enabling, but this argument is not persuasive. In order to be an anticipating reference, the reference must enable one of ordinary skill in the art to make and use the claimed invention without undue experimentation. *See Elan Pharmaceuticals, Inc. v. Mayo Foundation,* 346 F.3d 1051, 1054 (Fed. Cir. 2003). TriPath contends that Tanaka I and II fail to adequately disclose how it calculates atypia grades. To be sure, Tanaka I and II do not

system, albeit optional, can anticipate TriPath's technology if it discloses the necessary elements. *See Upsher-Smith*, 412 F.3d at 1322.

The 10-cell system, however, does not appear to "obtain" a second image and thus it is not anticipatory. The system operates by "call[ing] out automatically into the microscopic optical field or CRT monitor" the ten cells with the highest atypicality rank. Tanaka I at 3305. The CYBEST 4 obtains one digital image of the object of interest. From this image, it conducts measurements, analysis, and classification. This same image is recalled and displayed by the 10 Cell System. Cytyc provides no evidence that another image of the "called out" cells is obtained. Without such evidence, the Tanaka references cannot

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disclose the precise weight to be given to each parameter, as determined by a simulation test. However, the references explain the formula that it uses to calculate the atypia grade and the scale, and this is sufficient for enablement. Tanaka I at 3302. Indeed, Tanaka I and II are more detailed in their disclosure than the '182 patent itself, which does not attempt to explain how the computer assigns values to cells based upon their likelihood of malignancy. *See* '182 patent, col. 13, ll. 17-23.

TriPath relies solely on Dr. Reynolds' Rebuttal Expert Report (Reynolds Opposition Decl., Ex. B) for its enablement argument. Cytyc seeks to strike the portions of the report that were untimely filed. Although the Reynolds' initial report offered a single sentence opinion on enablement (generally relating to all the references in the case), the Rebuttal Report included a new lengthy discussion on Tanaka I and II. TriPath responds that Cytyc is neither surprised nor prejudiced by Dr. Reynolds' explication of the enablement issue because he discussed it in his initial expert report and Cytyc questioned him on the subject at his deposition. At this late stage in the litigation, TriPath may not submit expert reports discussing issues that should have been raised earlier. Consequently, paragraphs 10-18 of the Reynolds Declaration are not admissible to prove enablement.

be found to anticipate steps (4) and (5) of claim 1 or the analogous limitations of claim 21.

It is true that neither Tanaka I nor Tanaka II were cited in the '182 patent or discussed in the file history, but this factor alone is not proof of invalidity.[32] Though the lack of consideration by the examiner weighs in Cytyc's favor, there is no evidence of anticipation here. *See SIBIA Neurosciences , Inc. v. Cadus Pharmaceutical Corp.,* 225 F.3d 1349, 1355-56 (Fed. Cir. 2000) ("While the presentation at trial of a reference that was not before the examiner does not change the presumption of validity, the alleged infringer's burden may be more easily carried because of this additional reference.").

In sum, the Tanaka references do not anticipate the asserted claims because they do not disclose obtaining a second image. Whether the 10-cell system is part of the classification process disclosed in Tanaka I and II is irrelevant to this determination.

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[32] As TriPath points out, the examiner did consider an earlier Tanaka article regarding the Cybest III, and concluded that it did not disclose obtaining and displaying a second image by scanning. *See* Tanaka, *et. al*, "Fundamental Study of Automatic Cytoscreening for Uterine Cancer: III. New System of automated apparatus CYBEST utilizing the pattern recognition method," *Acta. Cytol.* 21, pp. 85-89 (1997). The consideration of the CYBEST III, however, is not particularly relevant to the Tanaka I and II anticipation analysis. The CYBEST III, unlike the CYBEST 4 described in Tanaka I and II, has no 10-Cell System feature. *See* Tanaka, *et. al*., CYBEST Model 3 Automated Cytologic Screening System for Unterine Cancer Utilizing Image Analysis Processing," *Analytical and Quantative Cytology*, Vol. 4, No. 4, Nov. 1982, pp. 279 -285. It is the 10-cell feature that Cytyc contends anticipates the asserted claims.

Consequently, TriPath's motion for summary judgment of nonanticipation will be granted and Cytyc's motion for summary judgment of invalidity will be denied.

VI. '327 PATENT (WILHELM)

The '327 patent claims a method for detecting machine or human errors in processing the slides for evaluation. TriPath has moved for summary judgment with respect to literal infringement of claim 1 and nonanticipation of claims 1-3, 5, and 6 of the '327 patent. Cytyc moved for summary judgment with respect to noninfringement of claims 2 and 5 only, and with respect to anticipation of claims 1 and 3.

A. Infringement

TriPath has conceded that, given the definitions of "normal" and "abnormal" set forth in the *Markman* Order, the TIS does not infringe claim 2. Thus, Cytyc's motion for summary judgment of noninfringement will be granted as to that claim. For reasons below, I will grant TriPath's motion for summary judgment with respect to literal infringement of claim 1 and grant Cytyc's motion for summary judgment with respect to infringement of claim 5.

1. Infringement of Claim 1

There is no genuine dispute that the Cytyc's TIS infringes claim 1 of the '327 patent. TriPath alleges that Cytyc's TIS conducts two suitability tests that infringe on claim 1: slide

vibration monitoring and fiducial mark verification.[33] Cytyc's only dispute is that TriPath has failed to show that the TIS uses "error flags, as opposed to some other kind of signal" as claimed in 1(d). TriPath has provided ample evidence, however, that the TIS system creates error flags and Cytyc provides no evidence to the contrary.

Dr. Bartel's opinion is sufficient evidence that the TIS utilizes error flags. An "error flag" is a mechanism that alerts the system or user when an error has been detected. *Markman* Order at 46. Bartel testified that Cytyc's slide vibration monitoring uses an accelerometer to monitor vibration levels in the processing machine, issuing a signal when the vibrations have

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[33] Claim 1 describes a method for checking the proper functioning of a slide processing device. It reads as follows:

> 1. A method of determining whether a slide processing system has suitably processed a biological specimen slide comprising the steps of:
> (a) processing the biological specimen slide with the slide processing system;
> (b) measuring at least one machine processing effectiveness parameter;
> (c) checking if the at least one machine processing effectiveness parameter has exceeded a limit; and
> (d) accumulating scan processing error flags.

Claim 3 depends upon claim 1, and add limitations relating to the steps 1(a) and (e). It provides:

> 3. The method of claim 1 wherein the scan processing error flags are generated by checking if the at least one machine processing effectiveness parameter is within a range.

Claim 5 is similar to claim 1, but requires "calculating at least one percentage of images acquired in focus on at least one predetermined number of tries."

exceeded a certain level. (Excessive vibrations can result in distortion of the image of the specimen slide.) Daniel Decl., Ex. 16 at C0018330. The accelerometer "provides a warning (or a slide or system error message) if acceleration levels exceed threshold values during the time an image is captured." *Id.* The System Hardware Electro-Mechanical Processor (SHEMP) records the number of counts for each slide and sends "an appropriate error message when a specified number of counts are exceeded for a given slide." Daniel Ex. 16 at C0018337.

TriPath also provides evidence that the fiducial mark verification system produces error flags. Fiducial marks, according to TriPath declarants, are "[a] collection of related blobs permanently printed on a ThinPrep Slide® configured such that an exact location on the slide can be identified by both the imaging system and humans." Daniel Decl., Ex. 21 at C0001796. If the fiducial marks are not properly aligned, the objects of interest may not be properly located. When reviewing a patient slide, TIS searches for the fiducial marks. If the marks cannot be found or are out of tolerance with the expected measures, a slide error is generated. "Slide errors" are logged in a local file and counted. If three consecutive slides have the same error, a "System Error" is generated.

Cytyc provides no evidence disputing these contentions. I do not see a material difference between a signal, a warning, and a flag, even though my *Markman* Order left open the possibility

that one exists. Cytyc makes no argument as to why the error signals and messages created by the TIS do not fall into the category of "error flags."[34] Thus, TriPath's motion for judgment on infringement of claim 1 of the '327 patent is granted.

2. Infringement of Claim 5

Claim 5 is the same as claim 1, except that part (d) requires "calculating at least one percentage of images acquired in focus on at least one predetermined number of tries" rather than "accumulating scan processing error flags."[35] The parties

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[34] At the hearing on these motions, Cytyc stated that "error flag" could refer to a specific kind of "computer variable," as opposed to a general warning signal, but admitted that the *Markman* construction was broader than this more technical definition. *See* Tr. at 35-36. This argument is not present in Cytyc's briefing. In any case, Cytyc seems to concede that my *Markman* construction sweeps in the kind of signals and warnings produced by the TIS.

[35] Claim 5 reads:

> 5. A method of determining whether a slide processing system has suitably processed a biological specimen slide comprising the steps of:
> (a) processing the biological specimen slide with the slide processing system;
> (b) measuring at least one machine processing effectiveness parameter;
> (c) checking if the at least one machine processing effectiveness parameter has exceeded a limit; and
> (d) calculating at least one percentage of images acquired in focus on at least one predetermined number of tries.

Claim 6 is similar to claims 1 and 5, except that it adds the limitation of calculating the percentage of images that were never adequately focused:

> 6. A method of determining whether a slide processing system has suitably processed a biological specimen slide comprising the steps of:
> (a) processing the biological specimen slide with the slide processing system;

do not dispute that the TIS performs (a) through (c) of the claim.

The only dispute is whether the TIS infringes part (d). The parties agree that TIS does "calculate a percentage" while determining the suitability of slides for slide processing. The dispute more particularly is whether the TIS calculates the precise percentage described in 5(d). Specifically, parties dispute whether the TIS calculates (1) "images acquired in focus" (the numerator), as a percentage of (2) a "predetermined number of tries" (the denominator).

I agree with Cytyc that the TIS does not calculate a number of images acquired in focus. Although I do not conclude that the TIS must calculate the "total" number of images acquired in focus -- because the claim does not require that the numerator be a total of anything -- it seems clear that the numerator must include only images that the machine has determined are in focus. The numerator in Cytyc's percentage, however, could include images that are not in focus. Thus, the TIS does not perform part (d) of claim 5.

By way of elaboration, I will set forth my rough understanding of Cytyc's focus-checking mechanism. The TIS has a microscope for looking at slides, with a camera as an eye. As

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(b) measuring at least one machine processing effectiveness parameter;
(c) checking if the at least one machine processing effectiveness parameter has exceeded a limit; and
(d) calculating a percentage of images that were never adequately focused.

the microscope is pointed at one part of a slide, the camera takes several pictures of the one part at various vertical distances from the slide as the microscope lens is slowly raised. The machine then gives a score to each of the pictures it has taken for that point, with a high score being more in focus and a low score being more out of focus. The image with the highest focus score is the one that the machine submits for checking.

After all the images taken from one slide have been submitted, the machine then calculates the percentage of "extreme plane" images in a slide relative to the number of focus attempts to make sure the percentage is not too high. An image is an "extreme plane" image if the highest focus score was given to that image when the microscope was at the lowest or highest plane it could achieve relative to the slide. These "extreme plane" images are not necessarily suitable for processing; they are the *most* in-focus images that the camera took for that part of the slide but they are not necessarily in focus enough to be processed. Because the extreme plane images are not necessarily suitable for processing, the TIS keeps track of how many of them there are in a slide. When the percentage of images reaches more than 30%, the slide as a whole is not suitable for processing.

The TIS technology does not calculate "images in focus." In fact, it seems to be doing the opposite. The TIS keeps track of extreme plane images precisely because they might be too out of focus for processing. Indeed, when the numerator reaches a certain percentage amount compared to the number of focuses

(30%), the machine deems the focus on the slide unsuitable for processing. Thus, the numerator must represent some amount of images that are not deemed "in focus" by the machine.

TriPath's arguments to the contrary are unpersuasive. Indeed, Tripath does not dispute the fact that the extreme plane images might not be in focus enough for processing. TriPath argues instead that when the percentage is below 30%, the TIS "treats" all the images as in focus because it continues to sends the slide for processing. But when the TIS sends a slide for processing, it does so with knowledge that part of the slide (up to 30%) might be out of focus. Thus, I do not agree that the TIS "treats" the extreme plane images as "in focus."

Relatedly, TriPath claims that the extreme plane images are "in focus" because they are the *most* in-focus images that the camera took for that portion of the slide. I disagree that the most in-focus images in a set qualify as "in focus" for the purposes of claim 5. The parties have not briefed the meaning of the term "in focus," and I agree with TriPath that the term is often used relatively (*i.e.*, an object can be more in focus than another). I interpret the term here, however, to mean "in focus enough for a particular purpose," the purpose in this case being slide processing. Under this definition, Cytyc's technology does not infringe.

TriPath has not provided evidence that the TIS calculates a

number of images "in focus" as a percentage of anything.[36] Thus, Cytyc's motion for summary judgment with respect to infringement of claim 5 is granted.

B. Anticipation

Cytyc moves for summary judgment that two prior art references anticipate claims 1 and 3 of the '327 patent: (1) the auto-focus technique of the Cerviscan system as described in an article by Tucker and Stark ("Tucker I");[37] and (2) the CDS-1000 WorkStation ("CDS-1000") as described by Dr. David J. Zahniser, who developed the CDS-1000 for Cytyc, by Dr. Trevor J. Darrell, and by four written documents.[38] TriPath has moved for summary

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[36] I do not address whether Cytyc's denominator qualifies as a "predetermined number of tries," because that would lead to a question of claim construction that has not been briefed by the parties.

[37] The full reference for Tucker I is Tucker & Stark, "A Focus Checking Technique for Image Analysis Systems," *Pattern Recognition*, Vol. 14, Nos. 1-6, pp. 231-37 (1981). In its initial memorandum, Cytyc argued that the '327 was anticipated by Tucker I and another article describing clinical trials of the Cerviscan system, Tucker & Husain, "Trials with the Cerviscan Experimental Prescreening Device on Polylysine-Prepared Slides," *Analytical and Quantitative Cytology*, Vol. 3, No. 2 (June 1981) ("Tucker II"). Cytyc suggests that Tucker II in combination with Tucker I was anticipatory, but never argued that Tucker II in itself was an anticipatory reference. Because a patent is anticipated only if each limitation is found in a *single* prior art reference, this memorandum addresses only Tucker I. *See IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1381 (Fed. Cir. 2005).

[38] The written documents are: "The ThinPrep Processor and the CDS-1000 Cytology WorkStation," Automated Cervical Cancer Screening Second Annual International Symposium, October 29-31, 1992, Atlanta, Georgia, pp. 1969-1991 ("CDS-1000 Article") (Daniel Ex. 11); CDS-1000 Source Code ("CDS-1000 Source Code"); CDS-1000 Cytology Workstation Operator's Manual ("CDS-1000 Operator's Manual") (Daniel Ex. 31); and CDS-1000 Image Analysis

judgment of nonanticipation with respect to claims 5 and 6. For reasons stated below, I will grant Cytyc's motion with respect to claims 1 and 3, I will grant TriPath's motion for summary judgment with respect to the CDS-1000, and I will deny TriPath's motion for summary judgment on anticipation of claims 5 and 6 by Tucker I.

1. Tucker I

The parties do not dispute that Tucker I discloses steps 1 through 3 of claims 1 and 3 of the '327 patent. The dispute is whether Tucker I discloses (1) the claimed steps for the purpose of determining "whether a slide processing system has suitably processed a biological slide sample" as required by the preamble of claim 1 and (2)"accumulating scan processing error flags" for the purpose of determining slide suitability as required by claim 1(d).

a. The Tucker I Technology

The Cerviscan system was an experimental[39] simulation system designed for the development of techniques for the automated prescreening of cervical cytology specimens. Tucker I at 231. Tucker, *et. al.*, developed a method for checking the focus of images by directly analyzing the data from a single scan. *Id.* Tucker's method uses a parameter called FOCWATCH that indicates

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Algorithms ("CDS-1000 Algorithms") (Daniel Ex. 30).

[39] TriPath has argued that an experimental system cannot anticipate. There is no authority for this proposition. 35 U.S.C. § 102 provides that any technology disclosed in a publication can anticipate a patent.

whether the image is in focus. *Id.* at 232. When an image is out of focus, the boundaries of the nuclei of the cells appear less defined. *Id.* FOCWATCH calculates the relative rate of change of scanner signals across those boundaries to indicate whether an image is in focus. *Id.*

Specifically, the focus-checking system operates by measuring the density difference between adjacent pixels as the scanner moves along the image. *Id.* at 236. A FOCWATCH value is computed using these measurements and that value is then compared to an average for the current specimen. *Id.* at 237. If the FOCWATCH value is less than a predetermined proportion of the average, an error signal is issued, and a focus correction routine is automatically triggered. *Id.* at 235, 237. If the focus is not correct, the system will give warning of the error and will initiate autofocus to correct the situation.

b. Disclosure by Tucker I of the Preamble of Claim 1

It is clear from the text of claim 1 alone that FOCWATCH discloses "a method for determining whether a slide processing system has suitably processed a biological specimen slide." There is no genuine dispute that keeping the imaging system in focus is a necessary part of slide processing suitability.[40]

[40] TriPath's assertion that FOCWATCH determines adequacy of a "field of view" rather than of a "slide" is irrelevant even if it is true. Claim 1 does not require that the technology measure the focus of a slide as opposed to a general field of view. It merely requires that the claimed technology measure a "machine processing parameter." '327 patent claim 1(b). FOCWATCH is such a parameter, as both parties concede. Even TriPath's expert, Dr.

TriPath argues, however, that the purpose of the FOCWATCH system is to check the focus of each image *before analysis begins*, and thus it cannot be a method for determining whether a slide *has been processed* suitably. In other words, TriPath argues that if the Tucker I FOCWATCH process is complete before slide processing has begun, it cannot help determine whether a slide has been processed correctly.

TriPath's argument is unsupported. There is no evidence that slide "processing" excludes the step of slide focusing. TriPath assumes that the processing described in claim 1 does not begin until after a slide has been focused and something called "analysis" begins. But the specification of '327 does not support this assumption, nor does the claim mention any distinct step called slide "analysis." The specification of '327 states that the focus measures are "measures of how well the automated cytology system has begun to process a slide and how it proceeds to process a slide." '327 patent col. 1 line 20-22. Under this description, focusing on a slide is necessary part of the processing of a slide.

The description of the preferred embodiment also supports an

Bartels, admitted that properly focusing the "system" is necessary for suitable slide processing:

> Q: And we agreed that maintaining a system in focus is part of suitably processing a slide, correct?
>
> A: Absolutely.

The fact that Dr. Bartels may not have been speaking specifically about Tucker I does not diminish the impact of his concession.

interpretation that slide processing includes focusing the slide. The preferred embodiment states that of the suite of suitability tests that the '327 patent claims, determining the percentage of "images focused" is part of "machine processing." *See* '327 patent col. 2 lines 40-44. Thus, I reject the proposition that Tucker I measures focus *before* slide processing. The fact that Tucker I discloses a method for determining whether the slide has been focused properly is sufficient to anticipate claim 1.[41]

c. Disclosure of "Accumulation of Scan Processing Flags" by Tucker I

The second issue that the parties contest with respect to the anticipation of claim 1 is whether Tucker I discloses a method for the "accumulation of scan processing error flags." I understand TriPath's arguments to be (1) that Tucker I does not teach "accumulating scan processing error flags" *for the purpose* of determining whether a slide has been processed suitably, and (2) that because the FOCWATCH error signal triggers an immediate refocusing of the scanner, it does not gather or collect error flags and thus it does not accumulate them.

TriPath's first argument is plainly without merit. If Tucker I discloses a method for accumulating scan processing error flags, it does it for the purpose of determining slide processing suitability. TriPath has been unsuccessful in

[41] TriPath's argument here is also inconsistent with its argument that Cytyc's slide vibration monitoring and fiducial marks determine whether a slide has been "suitably processed," insofar as both of those processes occur in the TIS prior to slide processing.

explaining the difference between generating an error message that the system needs refocusing and generating an error message that a slide is not in focus. As discussed above, determining whether the system is in focus is a necessary part of determining whether a slide has been processed properly.

TriPath's second argument that Tucker I does not disclose "accumulating" error flags is also unpersuasive. First, the FOCWATCH process does not ever seem to collect more than one error flag for checking machine processing. However, given the way I construed "accumulating" in my *Markman* Order at 43, 70 to mean "gathering or collecting *one or more* things," (notably, this is the way TriPath urged me to construe it), this does not appear material. Tucker I certainly discloses the generation of an error flag. As Cytyc points out, the literature uses the precise term "error flags." It discloses the use of that error flag to initiate a system to correct the focus of the machine. Thus, it appears Tucker I teaches accumulation of an error flag, albeit only one, for the purpose of determining whether a slide has be processed suitably.

TriPath also seems to be arguing that Tucker I fails to disclose "accumulation" because it does not "gather or collect" its error flag. TriPath's expert claims that "accumulating error flags would serve no purpose in the Tucker I method of focus correction" because "an error signal generated by FOCWATCH commences a focus correction routine." The import of this statement is obscure but appears in part intended as a back door

argument to avoid the construction of "accumulate" TriPath urged me to adopt in the *Markman* hearing. *See Markman* Order at 41.

I find the evidence clear and convincing as a matter of law that Tucker I anticipates claim 1(d). There is no question as to whether the FOCWATCH process gathers and accumulates an error flag for the purpose of determining slide processing suitability. Thus, I will grant Cytyc's motion for invalidity of claims 1 and 3 of the '327 patent.

d. Anticipation by Tucker I of Claims 5 and 6

The only argument that TriPath has offered with respect to claims 5 and 6 is that Tucker I does not disclose a system for determining whether a slide "has been suitably processed" because it operates before image analysis commences. I have already rejected this argument; consequently, TriPath's motion for summary judgment of nonanticipation of claims 5 and 6 by Tucker I will be denied.

2. CDS-1000

I grant TriPath's motion of nonanticipation by the CDS-1000 because there is insufficient evidence that it is prior art under 35 U.S.C. § 102(b).

As described in the discussion of the '377 patent, Section IV.B.4., *supra*, the CDS-1000 was a computer screening system that automatically located, measured, and analyzed every cell and cluster on a cervical slide and provided a cytologic status report for each patient. The parties dispute whether the CDS-1000 qualifies as prior art. TriPath contends that the CDS-1000

is not prior art because it was never publicly displayed before September 20, 1994, the effective filing date of the asserted claims. In order to anticipate a patent claim, the invention must have been known, used, or described in a printed publication before the applicant invented it, or a public display must occur more than one year prior to the filing of the patent application. 35 U.S.C. §§ 102(a), 102(b). Thus, the question is whether the CDS-1000 was publicly displayed before September 20, 1993.

Cytyc has provided testimonial evidence by a Dr. Zahniser that this CDS-1000 was publicly displayed four times prior to 1993: first, in October 1990 at a meeting of the American Society of Clinical Pathologists in Dallas, Texas; second in November 1990 at a meeting of the American Society of Cytology in Washington, DC; third in meetings of those organizations in the Fall of 1991; and fourth at the Automated Cervical Cancer Screening Symposium in Denver, Colorado from October 17-19, 1991. Zahniser claims that demonstrations of the CDS-1000 analyzing a PAP smear slide were shown at the first three meetings and demonstrations of a working CDS-1000 was shown at the Denver meeting. He claims that demonstrations of the CDS-1000 were also made at the Second Annual International Symposium of Automated Cervical Cancer Screening in Atlanta, Georgia from October 29-31, 1992, and a paper was delivered describing the CDS-1000. Dr. Zahniser also claims that he described the CDS-1000 prior to the fall of 1990 to at least four potential customers and many

hospital laboratories. It is not clear from his testimony whether the CDS-1000 disclosed each of the limitations of the asserted claims when it was publicly displayed.

Regardless, without corroborating evidence of the public display, Zahniser's testimony alone cannot support a finding of invalidity. *See Finnigan Corp. v. Int'l Trade Commission,* 180 F.3d 1354, 1368-69 (Fed. Cir. 1999) ("[C]orroboration is required of any witness whose testimony alone is asserted to invalidate a patent, regardless of his or her level of interest.").[42] In order for evidence to corroborate testimony, it must corroborate a material portion of that testimony. For example, evidence corroborating Dr. Zahniser's statements that he was present at the meetings is not corroboration that he publicly displayed the technology. Nor is it corroborating evidence that papers describing the CDS-1000 existed, unless there is also corroborating evidence that the papers were handed out during a demonstration during the relevant time. To survive summary judgment, Cytyc must produce some evidence other than Zahniser's testimony supporting an inference that the CDS-1000 was displayed publicly before September of 1993.

Cytyc's four pieces of documentary evidence do not

[42] TriPath asserts that Dr. Zahniser is an interested witness. TriPath points out that Dr. Zahniser was the scientific director at Cytyc during the period addressed by his declaration, and is now a Cytyc shareholder and consultant. In any case, as stated above, his testimony must be corroborated in order to invalidate a patent.

corroborate the public display of the patent. A paper was presented at the Georgia convention in 1992 ("CDS-1000 Article"). The CDS-1000 Article provides a fairly detailed description of the CDS-1000, but it does not describe any apparatus for testing slide suitability and does not corroborate Dr. Zahnizer's testimony that the machine was publicly demonstrated. Similarly, the CDS-1000 Operator's Manual and Source Code provide a functional overview of the CDS-1000 that shows no slide suitability test or proof of public display.

The CDS-1000 Algorithm is also not corroborating. It provides a written description of an autofocus algorithm used to find the initial focal position of the cell specimen once the slide has been loaded onto the stage. The CDS Algorithm, dated February 4, 1992, and marked "Cytyc Confidential," contains no evidence to corroborate Dr. Zahniser's testimony as to when the machines were displayed and what features those machines contained. Consequently, I find the CDS-1000 is not prior art and TriPath's motion for summary judgment of nonanticipation will be granted with respect to the CDS-1000.

VII. '969 PATENT (KAMENTSKY)

The '969 patent claims, among other things, a method and apparatus for networking microscope systems so that they may be able more easily to share slide information. Cytyc has moved for summary judgment with respect to noninfringement of independent

claim 16 and dependent claims 17 and 21.[43] TriPath has filed a motion for summary judgment that the asserted claims are not invalid as anticipated by prior art.

A. Infringement

Cytyc's motion for judgment as a matter of law that its TIS

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[43] Independent claim 16 reads:

> A network of interconnected microscope stations comprising:
> (a) a means for operatively linking microscope stations; and
> (b) a plurality of microscope stations connected to the means for operatively linking microscope stations, wherein a microscope of the plurality of microscope stations includes:
> (i) a movable slide stage for mounting a specimen slide having a specimen;
> (ii) a means for computing wherein information relating to the specimen slide being examined by the microscope is stored by the means for computing and is made accessible to other microscopes; and
> (iii) means for automatically recording location information of interest of the movable slide stage during a microscope examination, wherein the automatically recorded location information of interest represents microscope viewing locations on the specimen slide that are locations of interest.

Claims 17 and 21 depend on claim 16, and add the limitations of a terminal for a database and a cell analysis instrument, respectively:

> 17. The network of claim 16, wherein each microscope station in the network of the interconnected microscope stations further comprises a terminal for a database having information relevant to appropriate examination of the slide specimen.

> 21. The network of claim 16, wherein the network further includes at least one cell analysis instrument and wherein at least one interconnected microscope station of the network of interconnected microscope stations further comprises a terminal for receipt of analysis from the cell analysis instrument.

does not infringe claim 16 will be denied. As stated more fully below, there is a genuine dispute of fact as to whether Cytyc's Review Scope "records location information of interest" during microscope examination.

Claim 16(b)(iii) teaches a quality-control method for determining whether a human has reviewed an entire image. The preferred embodiment of the claim marks positions on a slide with a dot per unit of time as the microscope travels over it. This information is stored, allowing someone to look at the slide information at a subsequent time and determine which portions of the slide had been looked at under microscope and for how long.

Claim 16 is a "means-plus-function" claim, meaning that the claim is limited in part by the function of the technology, and is governed by 35 U.S.C. § 112(6). In order to prove infringement of such a claim, the party asserting infringement must show "the assertedly equivalent structure performs the claimed function in substantially the same way to achieve substantially the same result as the corresponding structure described in the specification." *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Intern, Inc.*, 389 F.3d 1370, 1378 (Fed. Cir. 2004) (internal quotation omitted). There is no dispute that the TIS's Review Scope is equivalent in structure to a "microscope station" or that the TIS performs steps 16(a) through (b)(ii).

The parties dispute only whether Cytyc's TIS performs a "means for automatically recording location information of

interest of the movable slide stage during a microscope examination" disclosed in claim 16(b)(iii). TriPath argues that the Review Scopes use a clock to record location information of interest automatically in three ways: (1) by recording errors in stage movement during review of areas of the slide; (2) by recording the areas that have been reviewed during operation of the Autoscan feature of the review scopes; and (3) by recording the location coordinates of the 22 areas of review.[49]

There is sufficient evidence to support an inference that the Autoscan function of the Review Scope records the location of the areas of interest during microscope review. The Autoscan is a function by which a human can prompt the TIS to perform a scan of an entire cell spot by marking one of the 22 cells presented by the Image Processor as suspicious. This "Autoscan" scans the entire cell spot, beginning at the top, and the cytotechnologist can select direction, speed, and type of movement. At any point, the human can interrupt the Autoscan and the Autoscan will resume from the point where it was interrupted so that no areas are missed. Notably, once the human pauses the Autoscan, the computer "updates" the Autoscan progress and calculates the "percent complete" of the scanned slide.

It is unclear whether the "updating" of the Autoscan and

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[49] "Automatically recording" means "recording without an instruction from the user to record." *Markman* Order at 73. "Location information of interest" refers to "the areas of the specimen slide that the reviewer has viewed through the microscope optics at a microscope station." *Id.* at 65.

calculation of "percent complete" entail simply the measuring of time elapsed, or whether they also entail recording the location of the microscope on the slide. Cytyc concedes that the TIS "tracks" the locations of the slide that have been viewed. The question is how it accomplishes this. If the machine notes the location of the microscope on the slide in the process of determining what percentage of the slide the reviewer has viewed, then it infringes claim 16. If it only measures time elapsed, it does not (even if time-elapsed is a proxy for location.)[50]

There is also sufficient evidence to support an inference that the Review Scope records location information of interest when it generates an RSW304 error. The RSW304 error, according to the requirement specification, alerts the system "if a stage access reported position does not reach the commanded position (+/- 4 microns) within 3 seconds during a move." In other words, this error signals that the microscope has failed to move from one preselected field of view to another within the specified time.

The machine must record the time that passes between each movement of the microscope during the Autoscan. The Review Scope is equipped with a clock, and the error messages generated by the TIS are logged with a date and time stamp. Given that the error depends on the degree to which the microscope has moved (+/-4

[50] TriPath has not raised a doctrine of equivalents argument with respect to this claim. Although recording time elapsed might be equivalent to recording location, it cannot literally infringe claim 16.

microns), the machine might also be recording the *location* of the microscope and where it is focused on the slide. Thus, the evidence is ambiguous as to whether the Review Scope records the location of the slide that the reviewer is on when it creates the error message. If it simply records the time elapsed (allowing the computer to infer whether the microscope is taking too long to reach a particular field of view), then it does not literally infringe. If it also records the location where the microscope has stalled, however, then it literally infringes claim 16.

TriPath's other arguments that the TIS infringes, however, are unavailing. Contrary to TriPath's contention, the recording of information that Cytyc concedes does occur is not done automatically. When a human operator reviews the 22 preselected fields of view, she can electronically mark suspicious objects on the slide. These coordinates are stored in the Review Scope's memory. After the human operator completes the examination, the computer will automatically recall the areas it had previously recorded at the human's instruction. Ultimately, however, it is the human operator who prompts the computer to mark and record areas of the slide. Thus, this function is not automatic.

TriPath's argument that the coordinate transformation within Autoscan infringes is also unsupported. TriPath asserts that when the TIS translates the 22 fields of view identified by the Image Processor into an x, y coordinate system to be read by the Review Scope, it automatically records location information of interest. The translation process requires adjusting the

coordinates and recording them. The stored coordinates are used, in conjunction with an internal clock, to control movement of the stage during review of the 22 fields of view. This recording process, however, occurs entirely before the human review process (not during microscope examination), and thus it falls outside of claim 16.

In sum, there is a dispute of fact as to whether Cytyc's TIS automatically records locations of interest during microscope review. Consequently, Cytyc's motion for summary judgment with respect to infringement of claim 16 of the '969 patent is denied.

B. Anticipation

TriPath has moved for summary judgment of nonanticipation of six references relating to the Highly Optimized Microscope Environment, or "HOME" system (collectively, the "HOME references").[51] Because none of the references disclose the

[51] The full references are: (1) Krief, Bruno, "HOME: Highly Optimized Microscope Environment, Concept et Development d'un Systeme de Microscopie Assistee par Ordinateur Applique a la Pathologie de Routine," PhD. Thesis, Joseph Fourier University (July 5, 1003) ("Krief Thesis") (Daniel Decl., Ex. 53 (French) and Ex. 54 (English)); (2) Brugal, Gerard, "IMPACT: Integrating Microscopy for Pathology Activities and Computer Technology," *Health and the New Communications Age*, M.F. Laires, *et. al.*, Eds., IOS Press, 304 -12 (1995) ("IMPACT Article") (Daniel Decl., Ex. 55); (3)Brugal, Gerard, *et. al.*, "HOME: Highly Optimized Microscope Environment," *Cytometry* 13:109-16 (1992) ("Cytometry Article") (Daniel Decl., Ex. 56); (4) Brugal, Gerard, *et. al.*, "HOME: Highly Optimized Microscope Environment," Advances in Medical Informatics, J. Noothoven van Goor and J.P. Christensen, Eds., IOS Press, 161-63 (1992) ("AIMI Article") (Daniel Decl., Ex. 57); (5) Morens, Annie, *et. al.*, "Tutorial: The HOME Microscope Workstation, A New Tool for Cervical Cancer Screening," Analytical and Quantative Cytology and Histology, Vol. 14, No. 4 (August 1992) ("Tutorial Article") (Daniel. Decl., Ex. 58); (6) Carl Zeiss AxioHOME Brochure ("AxioHOME Article")

structure for a "means of automatically recording" as required by my construction of claim 16, I will grant TriPath's motion.

1. The HOME Technology

The HOME system is a computerized microscope that looks like a conventional microscope with a mouse attached. Cytometry Article at 109. The microscope stage is manually, as opposed to automatically, controlled. *Id.* at 111. The user looks through the microscope and sees computer-generated texts and graphics in addition to the cells on the slide. *Id.* at 110. The user uses the mouse to mark objects of interest on the cell image and to control the computer software through menus and buttons. *Id.*

The microscope stage is equipped with encoders that allow the computer to read the position of the stage at any time. *Id.* at 111. Another encoder enables the computer to relocate objects of interest after they have been marked by the user. *Id.* at 114. In the "stage tracking" feature, the track of the microscope stage can be shown during the scan of a specimen slide. *Id.* The human operator can then see what percentage and which parts of the slide have so far been examined. *Id.*

The HOME system can be used for marking objects for record-keeping or examination by other personnel, carrying out morphometric measurements, counting tasks, and teaching. *Id.* at 115. Several microscope workstations and data entry stations can also be networked together to share information. *Id.* at 115-16.

(Daniel Decl., Ex. 59).

TriPath contends that the HOME references do not anticipate because they lack "means for automatically recording location information of interest," "means for operatively linking," "means for computing," and with respect to claim 21, a "cell analysis instrument." Cytyc responds that the HOME system operates with an internal clock that satisfies the means for automatically recording, and discloses a typical computer network that meets the requirement of "means for operatively linking." Before analyzing these arguments on their merits, I first address the question of whether all the references qualify as prior art.

2. Qualification of the IMPACT and Krief Articles as Prior Art

The parties dispute whether the IMPACT Article and the Krief Thesis are prior art. For reasons stated below, there is sufficient evidence supporting the conclusion that the two references constitute prior art.

a. IMPACT Article

The patent application resulting in the issuance of the '969 patent was filed on January 11, 1996. The critical date for determining whether a reference is prior art under 35 U.S.C. §102(b) is one year prior to the filing date -- here, January 11, 1995. Under section 102(a), the critical date is the date of invention. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996). A reference will not constitute prior art if (1) prior to the date of publication, the invention was conceived and reduced to practice; or (2) the invention was conceived prior to

publication of the reference and diligently reduced to practice afterwards. *Id.* at 1576-78.

TriPath contends that the '969 patent was reduced to practice no later than May 22, 1995. It points to a stock offering memorandum and three press releases discussing the "Pathfinder System," a commercial embodiment of the '969 patent. The stock offering memorandum, dated November 2, 1995, describes the Pathfinder system in detail and shows it connected to a system of other Pathfinders, a network server, and the Pathfinder DS. One press release, dated May 22, 1995, discusses the use of the Pathfinder at three hospitals. Another press release, issued on June 12, 1995, stated that the Pathfinder had been placed in a Pennsylvania hospital and would be available to the general public in September 1995. A July 17, 1995, press release stated that the Harvard Community Health Plan had begun testing a Pathfinder product. These press releases, TriPath claims, corroborate the testimony of co-inventor Mark Weissman that the Pathfinder was used in Beta test sites, available for sale in September 1995, and equipped with networking capability in 1995.

Cytyc claims that the press releases are insufficient to corroborate the inventors' testimony because they do not disclose a network of systems; they merely describe individual microscope stations with some information handling capabilities.

The diagram of the Pathfinder network in the stock offering memorandum clearly discloses a network of microscope stations that adequately corroborates the inventor's testimony. Thus,

TriPath has provided sufficient information for a jury reasonably to find that the '969 patent was reduced to practice in 1995. The publication date of the IMPACT article is September 25, 1995. The question of whether the IMPACT article constitutes prior art, therefore, is a triable issue.

b. Krief Thesis

TriPath contends that the Krief Thesis is not prior art because there is no proof that it is a "printed publication" for purposes of §102. A doctoral dissertation must be accessible to the public in order to be considered prior art. *In re Cronyn*, 890 F.2d 1158, 1161 (Fed. Cir. 1989) (holding that three student theses were not prior art because they were neither catalogued nor indexed in a meaningful way). Cytyc, however, presented evidence in its supplemental briefing to the summary judgment hearing that Krief was publicly available by July 20, 1994. Thus, there is a genuine dispute of fact as to whether the Krief Thesis qualifies as prior art.

3. "Means for automatically recording"

There is, however, not sufficient evidence supporting an inference that the HOME references anticipate a "means for automatically recording." As previously construed, a structure with a "means for automatically recording location information of interest" is a "personal computer that is part of a microscope station having an internal clock for automatically recording the location information of the stage (and, consequently, the slide) at regular clock intervals, and equivalent structures." *Markman*

Order at 63-66. None of the six references disclose this structure and function.[52]

Cytyc suggests that the stage tracking function, which informs the computer of the x and y coordinates of areas of the slide that were visited during screening, involves "automatically recording location information of interest." While this stage tracking arguably meets the required function, there is no evidence that it is accomplished by an internal clock that records at regular intervals.

Cytyc's expert opines that the HOME computer, like all computers, is synchronized to an internal clock. He explains that the clock signal is used to coordinate the actions of two or more circuits. Dr. Brugal's opinion may be accurate, but I cannot properly consider it for purposes of anticipation. An internal clock is not disclosed or taught in any of the

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[52] The parties debate whether the '969 patent is entitled to a heightened presumption of validity because of the fact that the Cytometry Article and the Tutorial Article are listed as prior art on the face of U.S. Patent 5,587,833 ("'833 patent") (Daniel Decl., Ex. 51), the parent to the '969 patent.

TriPath contends that, as a result of the PTO's consideration of the two references during prosecution of the '833 patent, the HOME system had already been reviewed as prior art with respect to the '969 patent, and the examiner's judgment deserves deference. The remaining four references, it claims, were merely cumulative of the two that were already considered in that they added "nothing new." Cytyc counters that the four additional references added significant detail over the other two, and the '969 examiner never indicated that he actually reviewed the prior art from the '833 application.

It is not necessary to resolve this dispute, however, because Cytyc has not produced sufficient evidence to create a genuine dispute of fact under the standard presumption of validity afforded by 35 U.S.C. §282.

references, and Dr. Brugal's testimony cannot be used to fill in the gap. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1577 (Fed. Cir. 1991) ("If it is necessary to reach beyond the boundaries of a single reference to provide missing disclosure of the claimed invention, the proper ground is not §102 anticipation, but §103 obviousness.").

4. "Operatively linked"

TriPath contends that although the HOME references teach the linking of stations in some fashion, they fail to disclose an "operatively linked" network of workstations as required by claim 16. Cytyc responds that the '969 patent does not require any particular type of network, and the references provide sufficiently detailed descriptions of a network to meet the asserted claim limitations.

Subparts (a) and (b) of claim 16 disclose a "means for operatively linking microscope stations." The relevant function is "operatively linking microscope stations," and the structure is a "PC LAN server and a twisted pair of wires, and equivalent structures." *Markman* Order at 73. To be "operatively linked" is to be "connected to perform an action." *Id.*

Each of the references makes some disclosure as to linking the microscope workstations together through a network server in order to share information. *See* Krief Thesis at 64; IMPACT Article at Fig. 2B; Cytometry Article at 115-16; AxioHOME Article at C0121648; AIMI Article at 162; Tutorial Article at C0122533.

These disclosures are sufficient to create a genuine dispute of fact regarding the anticipation of the HOME references on this claim limitation.

5. "Means for computing"

TriPath contends that the HOME references fail to disclose claim 16(b)(ii)'s requirement of "means for computing wherein information relating to the specimen slide being examined by the microscope is stored by the means for computing and is made accessible to other microscopes." Specifically, it argues that although the HOME system discloses workstations that have a computer for storing information, it does not necessarily follow that the stored information relates to the slide being examined and is "made accessible" to other HOME workstations. Cytyc has not addressed this question.

Some of the references arguably disclose the storage of information related to the slide, *see* Krief Thesis at 194, Cytometry Article at 114, Tutorial Article at 290, IMPACT Article at 306, but only the Krief Thesis teaches that this information is available to other microscopes in the network. Krief Thesis at 194. Consequently, a genuine dispute of fact exists as to "means for computing" only with respect to the Krief Thesis.

6. "Claim 21"

Because claim 16 was not anticipated, it follows that claim 21, which depends on claim 16, also was not.

Even if claim 16 were anticipated, however, it is clear that

Claim 21 was not. Claim 21 adds to the network of claim 16 the limitation of a "cell analysis instrument." A "cell analysis instrument" is "a device, not including a microscope station, that performs measurement or analysis of at least one cell feature on a specimen preparation, such as a specimen slide." *Markman* Order at 71. The HOME workstation is not such a device. Human operators perform analysis at the HOME microscope station, but no separate cell analysis equipment is disclosed in any of the references.

In sum, although the HOME references arguably disclose "operatively linking" and the Krief Thesis arguably discloses "means for computing," none of the references disclose "means for automatically recording location information of interest." Thus, summary judgment of nonanticipation for TriPath is granted.

VIII. CONCLUSION

As more fully set forth above,

With respect to the '377 patent:

1. Cytyc's motion for summary judgment as to noninfringement (Docket No. 157) is DENIED;

2. Cytyc's motion for summary judgment as to invalidity (Docket No. 157) pursuant to §102 is DENIED;

3. TriPath's motion for summary judgment of nonanticipation (Docket No. 161) is DENIED with respect to the Tanaka references, and GRANTED with respect to the Husain references, Greenberg, and the CDS-1000.

4. Cytyc’s Motion to Strike paragraphs 9-12 of Russ’ Updated

Expert Report (Docket No. 142 at Prayer 2) is GRANTED insofar as it is offered to prove a theory of infringement based upon the doctrine of equivalents and otherwise DENIED.

With respect to the '182 patent:

1. TriPath's motion for reconsideration (Docket No. 239) is DENIED;

2. Cytyc's motion to strike (Docket No. 214) is GRANTED in part and DENIED in part.

3. Cytyc's motion to strike (Docket No. 142 at Prayer 1) is DENIED as moot in light of Docket No. 214;

4. Cytyc's motion for summary judgment of noninfringement (Docket No. 169) is GRANTED;

5. Cytyc's motion for summary judgment of invalidity (Docket No. 169) pursuant to §102 is DENIED;

6. TriPath's motion for summary judgment of nonanticipation (Docket No. 153) is GRANTED.

With respect to the '327 patent:

1. TriPath's motion for summary judgment as to literal infringement of claim 1 (Docket No. 156) is GRANTED;

2. Cytyc's motion for summary judgment of noninfringement (Docket No. 175) is GRANTED with respect to claims 2 and 5;

3. Cytyc's motion for summary judgment of invalidity with respect to claims 1 and 3 (Docket No. 175) is GRANTED;

4. TriPath's motion for summary judgment as to nonanticipation to claims 5 and 6 (Docket No. 156) is DENIED with respect to Tucker I and GRANTED with respect to the CDS-1000.

With respect to the '969 patent:

1. Cytyc's motion for summary judgment of noninfringement (Docket No. 164) is DENIED;

2. TriPath's motion for summary judgment of nonanticipation (Docket No. 149) is GRANTED.

3. Cytyc's motion to strike (Docket No. 142 at Prayer 3) is GRANTED.

/s/ Douglas P. Woodlock

DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE

Appendix: Summary of Revised and Additional Claim Construction

Term	**Court Construction**
comprising ('377 patent, claims 11 and 16)	including but not limited to
classifying the specimen ('377 patent, claims 11, 16)	assigning the entire specimen or objects within the specimen into one of two or more groups
interactive review ('377 patent, claim 11)	examination by a final classifier, human or otherwise, of results from an initial classification of a specimen or objects within the specimen *Term is claim limiting.
in focus ('327 patent, claim 5)	sufficiently in focus for a particular purpose